SECOND AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

1. This is an action, brought by Relator Justin Dillon ("Relator"), to recover damages and civil penalties on behalf of the United States of America, and numerous state and local governments, arising out of false claims and records presented to the United States of America, to various States identified in Paragraph 2 below, the District of Columbia, and the Cities of Chicago and New York (the "*Qui Tam* States") by Defendant Incyte Corporation ("Incyte").

2. This action arises under the provisions of Title 31 U.S.C. §3729 *et seq*., popularly known as the False Claims Act (the "FCA"), and pursuant to analogous provisions of state and local law, including, but not limited to, the following:

- Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901
- California False Claims Act, Cal. Gov't Code § 12651 *et seq*.
- California Insurance Frauds Prevention Act, California Insurance Code § 1871.7 *et seq*.
- Colorado Medicaid Assistance Act, Rev. Stat. § 25.5-4-304 *et seq.*
- Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq.*
- Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201 *et seq.*
- Florida False Claims Act, Fla. Stat. § 68-081 *et seq.*
- Georgia False Medicaid Claims Act, Ga. Code § 49-4-168 (2007)
- Hawaii False Claims Act Against the State, Haw. Rev. Stat. § 661-21 *et seq.*
- Illinois False Claims Act and Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 *et seq.*
- Illinois Insurance Claims Frauds Prevention Act, 740 Ill. Comp. Stat. § 92
- Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*
- Iowa False Claims Act, Iowa Code § 685.1 *et seq*.
- Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.1 *et seq.*
- Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-6-1 *et seq.*
- Massachusetts False Claims Act, Mass Laws Ch. 12, § 5(A) *et seq.*
- Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq.*
- Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*

- Montana False Claims Act, Mont. Code § 17-8-401 *et seq.*
- Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.010 *et seq.*
- New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*
- New Mexico Medicaid False Claims Act., N.M. Stat § 27-14-1 *et seq.*
- New Mexico Fraud Against Taxpayers Act, N.M. Stat. § 44-9-1 *et seq.*
- New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq.*
- North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*
- Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053 *et seq.*
- Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*
- Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*
- Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-181 *et seq.*
- Texas Medicaid False Claims Act, Tex. Hum. Res. Code § 36.001 *et seq.*
- Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.*
- Washington Medicaid Fraud False Claims Act, RCW 74.66.020
- Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq.*
- District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.*
- City of Chicago False Claims Ordinance, Mun. Code, § 1-22-010 *et seq.*
- City of New York City False Claims Act, Adm. Code § 7-801 *et seq.*

(collectively, "State False Claims Acts").

3. These false or fraudulent claims for reimbursements were submitted, or caused to be submitted, by Defendant and/or other entities or individuals to government-funded healthcare programs including, without limitation, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration[1] for Jakafi® (ruxolitinib), a blockbuster prescription drug manufactured, promoted and sold by Incyte.

4. The United States of America, and the above-named States and Cities, are the plaintiffs for whom recovery is sought for false and fraudulent claims submitted to Government Healthcare Programs, as well as those of the respective State and City Plaintiffs.

5. To enrich itself at the expense of the federal Government, as well as the respective State and City Plaintiffs, Incyte engaged in multiple, intertwined unlawful marketing

[1] These government-funded healthcare programs are collectively referred to as "Government Healthcare Programs."

schemes related to the promotion, marketing, prescribing, and/or sale of Jakafi. First, Incyte paid for and deployed nurse educators to recommend Jakafi to prescribing physicians, as well as to promote Jakafi directly to patients, in a form of improper "white coat" marketing. Second, Incyte has operated a "speaker program" through which it has paid prescribing physicians to give speeches about Jakafi to physicians and other healthcare professionals as remuneration for prescribing Jakafi. Third, Incyte paid tens of millions of dollars to various foundations and patient assistance programs to serve as conduits for the foundations and funds to pay the copay obligations of thousands of Medicare patients taking Jakafi, and to illegally induce those patients' purchases of Jakafi, thereby increasing the number of Jakafi prescriptions being written.

I. PARTIES

6. Relator-Plaintiff Justin Dillon formerly served as the Senior Director - US Region Compliance Lead & Assurance Services for Defendant Incyte until October 2018.

7. Upon information and belief, Relator was terminated by Incyte after raising numerous compliance issues with Incyte management over the course of several years.

8. Relator is, and at all times was, a citizen and resident of the Commonwealth of Pennsylvania.

9. Relator brings this action on his own behalf and on behalf of the United States, and the above-named States and Cities, pursuant to 31 U.S.C. § 3730(b)(1) and the respective State and City whistleblower statutes cited in paragraph 2 of this Second Amended Complaint.

10. Relator worked for Incyte for more than three years and has more than 22 years of experience in the pharmaceutical industry, including 12 years in compliance.

11. Defendant Incyte Corporation ("Incyte" or the "Company") is a Delaware corporation with principal executive offices located in Wilmington, Delaware. Incyte is a

biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs.

12. Incyte's only commercial product is, and at all relevant times was, Jakafi® (ruxolitinib).

13. Incyte obtained U.S. Food and Drug Administration ("FDA") approval for the distribution and sale of Jakafi in November 2011 for the treatment of intermediate or high-risk myelofibrosis (MF), a life-threatening bone marrow disorder.

14. Myelofibrosis is a disorder of the bone marrow in which the marrow is replaced by scar (fibrous) tissue, which can result in death.

15. After Incyte received FDA approval for Jakafi in November 2011, and following significant market and clinical research, the Company immediately launched the drug for sale. While the FDA approved Jakafi for treatment of intermediate or high-risk myelofibrosis, Defendant recognized that, initially, the drug's core patient group would be the severely-ill patient population. This was due to the fact that myelofibrosis was a slow developing disease that evidenced few symptoms at the outset, leading physicians to treat the disease with a "wait and see" approach and only consider employing Jakafi when a patient reached more advanced stages.

16. In December 2014, the FDA approved Jakafi for the treatment of patients with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea, the standard treatment for PV. Jakafi is the first and only product approved by the FDA for PV, a rare and progressive blood cancer.

17. The number of patients for each condition is relatively small: 100,000 for PV[2] and less than 20,000 for MF.

[2] The company admittedly estimates that only about 25% of the 100,000 PV patients in the U.S. are

II. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confer jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

19. This Court has supplemental subject matter jurisdiction over Defendant's violations and the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 3732(b) because Defendant's violations of the State False Claims Acts and/or the federal FCA arise out of a common nucleus of operative fact. *See also* 31 U.S.C. § 3732(b) (conferring district court jurisdiction over any action brought under the laws of any state for the recovery of funds paid by a state if the action arises from the same transaction or occurrence as an action brought under the federal FCA).

20. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district.

21. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c) because Defendant transacts business within this District and because acts proscribed by 31 U.S.C. § 3729 occurred within this District.

III. PRELIMINARY STATEMENT

22. In accordance with 31 U.S.C. § 3730(b)(2) and previous Orders of this Court, this Second Amended Complaint is being filed under Seal.

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eligible for treatment with Jakafi.

23. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730(e)(4)(A), amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010) ("PPACA"). Moreover, Relator affirmatively disclosed his allegations to the United States Attorneys' Office for the Eastern District of Pennsylvania prior to filing this action.

24. To the extent there has been a public disclosure of the information upon which the allegations of this Second Amended Complaint are based that is unknown to Relator, Relator is an "original source" of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by the PPACA, *supra*, and similar state law provisions.

25. Relator possesses direct and independent knowledge of the information in this Second Amended Complaint by virtue of his role as a former employee of Incyte.

26. Relator's counsel voluntarily provided the United States with information related to this claim prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

IV. APPLICABLE FEDERAL LAW

A. Federally-Funded Healthcare Programs

27. The Medicare Program ("Medicare") is a health insurance program administered by the Government of the United States that is funded by taxpayer revenue. Medicare is directed by the U.S. Department of Health and Human Services ("HHS"). Medicare was designed to assist in providing medical services and durable medical equipment to persons over sixty-five (65) years of age and certain others who qualify for Medicare because of disability or end stage renal disease. Generally speaking, if one is eligible for Medicare, Part A covers hospital, inpatient, nursing home, and other institutional care; Part B covers doctor visits and outpatient services; and Part D provides prescription drug coverage.

28. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396- 1396v (hereafter, "Medicaid"), is a health insurance program administered by the Government of the United States and the various individual States and is funded by state and federal taxpayer revenue. The Medicaid program is overseen by the HHS through its Centers for Medicare and Medicaid Services ("CMS").

29. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to, among others, financially needy individuals that qualify for Medicaid. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

30. Federal funding for the Medicaid program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, copayments, co-insurance, and deductibles. The Medicare Savings Programs consist of the

Qualified Medicare Beneficiary (QMB) Program, 42 U.S.C. §1396d(p)(1), the Specified Low Income Medicare Beneficiary (SLMB) Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual (QI) Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals (QDWI) Program, 42 U.S.C. § 1396d(s).

31. There are a number of other health insurance programs funded by the federal government. Among these are the following:

a. the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the federal government. TRICARE/CHAMPUS pays for, among other items and services, medical devices, and surgeries for its beneficiaries.

b. the Federal Employees Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. It pays for, among other items and services, medical devices and surgeries for its beneficiaries.

In addition, the federal government operates hospitals, including through the Department of Defense and the Department of Veterans Affairs.

B. The False Claims Act

32. The federal False Claims Act, as amended by the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 provides, in relevant part:

> **Liability for Certain Acts**. (1) In General – Subject to paragraph (2), any person who – (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B)…or (G). . . or (G) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil

> penalty of not less than [$10,781.00] and not more than [$21,563.00] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

33. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2), and (7).

34. The FCA empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. 31 U.S.C. § 3730(b)(1). The FCA complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

35. The FCA also imposes liability upon persons who knowingly make, or cause to be made, a false record or statement material to a false claim, as well as persons who conspire to "defraud the Government by getting a false or fraudulent claim allowed or paid." 31 U.S.C. §§ 3729(a)(2) and (a)(3).

36. The FCA, 31 U.S.C. § 3729(b)(1), provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

37. The FCA, 31 U.S.C. § 3729(b)(4), provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

38. Prior to 2016, the last increases to the penalties for FCA violations occurred on August 30, 1999 and changed the minimum from $5,000.00 to $5,500.00 and the maximum from $10,000.00 to $11,000.00, plus treble damages. 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999). On August 1, 2016, the U.S. Department of Justice published Interim Final Rules, which significantly increased penalties under the False Claims Act for the first time in nearly eighteen years. Now, for violations occurring after November 2, 2015, the new minimum and maximum penalties are $10,781.00 to $21,563.00 plus treble damages. 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016). These penalties increased to $11,181 to $22,363 per violation in 2018, effective January 15, 2018. 83 Fed. Reg. 3944 (January 29, 2018).

C. The Federal Anti-Kickback Statute

39. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A) and (B) ("AKS"), prohibits offering to pay or paying any remuneration to any person to induce such person "to purchase . . . any good . . . service, or item for which payment may be made in whole or in part under a federal healthcare program" or "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program."

40. Pursuant to the AKS, it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product or service (including diagnostic services) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid and TRICARE. The statute has been interpreted to cover any arrangement

where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert denied*, 474 U.S. 988 (1985). In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

41. In *McNutt ex rel. U.S. v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) (herein "*McNutt*"), neither party disputed that complying with federal healthcare laws, including the AKS, was a condition for payment by CMS. "'The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.' *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). The violation of the regulations and the corresponding submission of claims for which payment is known by the claimant not to be owed make the claims false under sections 3729(a)(1) and (3)." Overall, *McNutt* demonstrates that violations of federal healthcare laws, including the AKS are considered material and form the basis of a false claim under the False Claims Act.

42. A violation of the AKS constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7b. The government may also assess civil money penalties, which could result in treble damages plus $50,000 for each violation of the AKS. 42 U.S.C. § 1320a-7a(a)(7).

43. Importantly, although the AKS does not afford a private right of action, the

federal False Claims Act provides a vehicle whereby individuals may bring *qui tam* actions alleging violations of the AKS. *See* 31 U.S.C. §§ 3729 *et seq*.

44. Compliance with the AKS is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (2010) (stating, in part, that a "claim that includes items or services resulting from a violation of . . . [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]. . . ."); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011) (stating "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare" and holding that "appellants, by alleging that appellees violated the AKS while submitting claims for payment to a federal health insurance program, have stated a plausible claim for relief under the FCA.").

45. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h). Proof on an explicit *quid pro quo* is not required to show a violation of the AKS.

46. When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a payment, which may take the form of a "copayment," "coinsurance," or "deductible" (collectively "copays").

47. The AKS prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare. *See* 42 U.S.C. § 1320a-7b.

V. BACKGROUND

A. Background of the Company

48. Incyte was founded in 1991 and is a biopharmaceutical company headquartered in Wilmington, Delaware. Incyte employs approximately 1,400 individuals and conducts its drug discovery, research, development, and marketing activities at its Wilmington headquarters.

49. Incyte describes its business as "the discovery, development and commercialization of proprietary small molecule drugs to treat serious unmet medical needs," focusing primarily in the areas of oncology and inflammation. Since 2003, Incyte has explored ways to inhibit enzymes called janus associated kinases (JAKs) that reside within cells. These enzymes control certain biological functions, and contribute to symptoms experienced by patients with various diseases.

50. While Incyte is working to develop various drug candidates, its first and only commercially available product is Jakafi (ruxolitinib).

51. Jakafi is an oral JAK inhibitor first synthesized by Incyte in 2005 to improve symptoms for patients with myelofibrosis.

52. Jakafi is extremely expensive; prescriptions can cost as much as $144,000.00 per year per patient.

53. Jakafi's sales have grown steadily since its 2011 approval. Its announced "net product revenues" are as follows:

- 2013 - $235 million

- 2014 - $358 million
- 2015 - $601 million
- 2016 - $853 million
- 2017 - $1.13 billion
- 2018 –$1.4 billion
- 2019 – Expected $1.58-$1.54 billion

54. Relator estimates that between 40 to 43% of the patients prescribed Jakafi receive care under Medicare or another Government Healthcare Program.

55. At this time, there are approximately 120 Incyte sales representatives promoting Jakafi nationwide.

56. Incyte has a number of different sales positions, which are described as follows:

	SALES	**ACCOUNT MANAGER**	**NURSE EDUCATOR**	**MEDICAL SCIENCE LIAISON**
Titles and Acronyms	• Oncology Therapeutic Specialist (OTS) • Oncology Account Specialist (OAS) • Oncology Business Director (OBD)	• National Account Manager (NAM) Payer & Patient Access • National Account Payer-GPO and Strategic Account	Oncology Clinical Nurse Educator (OCNE or ONE)[3]	MSL
Division	Sales	Market Access	Product Strategy	Medical Affairs
Customers	Individual Healthcare Professionals	• IDPNs • Health Plans • Employers • GPOs	• Allied Health Professionals • aHCP Organizations	Individual Healthcare Professionals

[3] Historically, this position reported into the Sales division and was recently transferred to Incyte's Product Strategy division.

			• Patient Advocacy Organizations • Patients	

B. Myelofibrosis and Jakafi

57. Myelofibrosis is a severe, life-threatening bone marrow disease afflicting between 16,000 and 18,500 patients in the U.S. Myelofibrosis disrupts the body's normal production of blood cells, resulting in extensive scarring to bone marrow, leading to severe anemia, weakness, fatigue, and often, an enlarged spleen and liver

58. Myelofibrosis is a type of chronic leukemia that can occur on its own (primary myelofibrosis) or as a result of another bone marrow disorder (secondary myelofibrosis).

59. Myelofibrosis has a poor prognosis and limited treatment options. According to Incyte, Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis.

C. Polycythemia Vera and Jakafi

60. Jakafi is indicated for treatment of patients with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.

61. PV is a slow-growing blood cancer in which the bone marrow makes too many red blood cells. *See* https://www.mayoclinic.org/diseases-conditions/polycythemia-vera/symptoms-causes/syc-20355850. These excess cells thicken the blood, slowing its flow, which may also cause complications, such as blood clots, which can lead to a heart attack or stroke. *See id.*

62. PV is a trilineage myeloproliferative neoplasm (MPN) characterized by increased myeloid, erythroid, and megakaryocytic cell proliferation. Hyperproliferation of these precursor

cells leads to elevated levels of red blood cells, white blood cells, and platelets. Splenomegaly is present in 30% to 40% of patients with PV.

VI. DEFENDANT'S MISCONDUCT

A. Incyte Has Paid Kickbacks to Potential Prescribers to Induce Them to Prescribe Jakafi

63. Since 2011, Incyte has operated a "speaker program" through which it has paid Jakafi prescribers to give speeches and other presentations about Jakafi to physicians and other healthcare professionals.

64. Incyte has pretended that these presentations were intended to provide potential Jakafi prescribers with substantive medical information about the drug. In reality, the vast majority of these events have been mere pretexts for paying thousands of dollars in sham speaking fees to prescribers for the purpose of inducing them to prescribe Jakafi.

65. Incyte's own Standard Operating Procedures include the statement that the "Speakers Bureau is owned by the Marketing Department."

66. S Phase, LLC is the third-party vendor that manages Incyte's speaker's bureau. S Phase is headquartered in Atlanta, Georgia.

67. For example, S Phase will order food for program attendees, even if the number of attendees is low (i.e., 3-4), and the Incyte sales representative orders and pays for food for the rest of the office staff that do not attend the program (these non-attendees can often number 10-20+ per office). At an October 2018 meeting, Bob Tunstall, Associate Director, Marketing, noted that "We have to feed the whole office or they won't let us do the program."

68. Many of these speeches have been attended only by the prescriber's own office staff, by close friends who have attended multiple presentations, or by people who were not medical professionals and had no legitimate reason for attending.

69. Moreover, the criteria for speakers in the Incyte Speakers' Bureau are virtually non-existent. Incyte sales representatives suggest/select speakers who are then routinely approved by Oncology Business Directors and/or Eric Vogel, Vice President, U.S. Sales. There is little to no "vetting" of the proposed speaker except for the submission of a c.v. to Incyte for the sole purpose of determining the speaker's compensation rate.

70. Additionally, many of the "speeches" do not involve any actual substantive presentation by the purported "speaker."

71. The events are often held in expensive restaurants with excessive amounts of alcohol and food.

72. Even an internal audit conducted by Incyte in August 2014 made the following conclusion – "The current execution of our Speaker Programs raises significant concerns as currently implemented."

73. The "Speaker Program Compliance Assessment Audit Report" also determined the following regarding Incyte's Speaker Program – "There are no compensating controls in place. As a result there is a significant risk of loss or undetected error."

74. Incyte has also provided kickbacks to prescribers in other forms. These include lavish meals and entertainment.

75. For example, as recently as September 2018, Relator is aware of an Incyte Oncology Therapeutic Specialist in New York City ("Sales Representative No. 1") violating Incyte's Policy on Engaging Healthcare Professionals and Organizations in the following manner:

a. Sales Representative No. 1 permitted Bruckner Oncology (2330 Eastchester Road, Bronx, NY 10469) to order the food for the in-office meal. Sales Representative No. 1 was not aware of what food and drink was ordered.

b. Sales Representative No. 1 did not attend the in-office meal but signed the sign-in sheet to indicate that he had attended.

c. Sales Representative No. 1 did not check to see what office personnel attended the meal.

d. Sales Representative No. 1 obtained the prescribing physician's signature on the sign-in sheet but the physician did not attend the meal.

76. Moreover, without solicitation by the provider, Sales Representative No. 1 discussed Incyte's ongoing graft-versus-host disease ("GvHD") clinical trial and offered to submit a Medical Information Request for the physician. Incyte is not approved for GvHD.

77. Sales Representative No. 1 reported to Incyte's compliance office that this type of conduct happens regularly in the majority of the accounts he calls on.

78. Other common problems at Incyte with sign-in sheets included:

a. The use of the phrases "did not sign" and "did not eat" by Incyte sales representatives was widespread. Further, Incyte sales representatives do not list healthcare prescribers on sign-in sheets if the prescriber requests to be omitted in order to hide value provided to prescribers by Incyte.

b. Incyte sales representatives regularly speak with a prescriber and then leave the office, but an expensive lunch or snack is delivered for the whole office after the sales representative has left. In some instances, a food delivery may even occur before the Incyte sales representative has arrived to speak with the prescriber.

c. Ongoing sign-in-sheet irregularities consistently cause Incyte to knowingly and falsely report under the Physicians Payment Sunshine Act, in addition to serving as kickbacks to the prescriber(s).

79. Many of the events for which Incyte paid its speakers were shams, with no physicians or other potential Jakafi prescribers present. Many of these events were attended only by Incyte representatives and/or the speaker's office staff. Many were, and continue to be, held at expensive restaurants.

80. Incyte provided these kickbacks to prescribers knowingly and willfully, in violation of the AKS. These kickbacks rendered false, within the meaning of the False Claims

Act, the claims for payment that were submitted to Government Healthcare Programs for Jakafi prescriptions that were written by kickback recipients subsequent to their receipt of the kickbacks.

81. As such, Incyte caused the submission of false claims to Government Healthcare Programs

82. Incyte manages between 750-800 speaker programs per year (i.e., 773 in 2017).

83. Spending, *not including compensation to the speakers*, for the food and beverage costs alone associated with these sham programs:

- 2014 - $4.1 million
- 2015 - $6.0 million
- 2016 - $5.7 million
- 2017 - $5.4 million
- 2018 - $3.1 million (as of May 2018)

84. In addition, speakers are reimbursed $3,000-5,000 per program.

85. The programs are purposefully broad and off-label questions are regularly encouraged.

86. Incyte recently terminated one of the company's 12 Oncology Business Director for violations related to the company's speaking programs.

87. For example, Jason Salganick, M.D., an oncologist from Phoenix, Arizona, has requested that Incyte register him for speaking programs in locations where Dr. Salganick intends to vacation. Incyte has complied.

88. Incyte drug representatives regularly pay upwards of $3,000 for office or clinic "lunches" with a high-frequency directed towards high prescribers.

B. Incyte Uses The Sponsorship of Events, Sales Conferences And Meetings To Flow Money To Prescribers And Provider Groups

89. Incyte regularly pays and/or management approves costly requests for Incyte to sponsor exhibits and displays.

90. These requests often far exceed Incyte's established fair-market value (FMV) rates.

91. For example, in 2016, Incyte paid more than $642,000 for various "Exhibits & Displays" across the country.

92. Sponsorship of events are generally handled and approved by Incyte's Patient Advocacy department. Patient Advocacy reported to Incyte's Marketing division until 2017 and now reports to the commercial side of Incyte.

93. Examples of Incyte's donations to various groups, entities and individuals are as follow:

a. October 26, 2015 – Incyte approved funding for Florida Cancer Specialist Foundation's Time to Remember Gala in the amount of $12,000.
    i. The Florida Cancer Specialists Foundation is a 501(c)(3) nonprofit organization that helps individuals with their essential living expenses while they undergo treatment for cancer. Cancer patients are able to receive assistance from this foundation for their non-medical bills, such as overdue rent, mortgage, utility bills and car payments. *See* http://foundation.flcancer.com/
b. 2015 – Multiple donations to Pancreatic Cancer Action Network.
    i. Donations in the amounts of $20,000, $5,000 and $5,000.
    ii. Jakafi does not have an indication for any solid tumor conditions, including pancreatic cancer.
c. June 2017 - Incyte made a $350,000 "charitable contribution" to the MPN Research Foundation for the "MPN Challenge."
d. January 29, 2017 – Incyte approved $10,000 in funding to Denali Oncology Group.

i. Request was submitted by Tim Bisson (Incyte Senior Director, National Accounts & Patients Services) and Shari Yamada (former Incyte National Accounts Manager) on behalf of the Denali Oncology Group.

ii. The description of the $10,000 donation was "2017 membership."

iii. The Denali Oncology Group is a group (not a medical practice) of medical oncologists and radiation oncologists serving patients in Alaska.

e. January 3, 2017 - Bob Tunstall (Incyte, Associate Director, Marketing)[4] requested $75,00 to sponsor a meeting at M.D. Anderson Cancer Center in Houston, Texas.

i. M.D. Anderson is Incyte's largest account.

ii. The event at issue was being managed by JWC Covenant, a third-party medical education organization that works exclusively with oncology providers.

f. February 7, 2017 - Bob Tunstall (Incyte, Associate Director, Marketing) requested $180,000 to sponsor three "State of the Science Summits" for OncLive.

i. OncLive describes itself as the official website for the Intellisphere, LLC Oncology Specialty Group, which publishes a number of oncology medical journals. "The mission of OncLive is to arm oncology professionals with the resources and information they need to provide the best patient care." *See* https://www.onclive.com/about-us.

ii. "State of the Science Summits" are sponsored by OncLive "to educate healthcare professionals on the clinical benefits associated with new science" relating to cancer care. *See* https://www.onclive.com/meetings/soss.

iii. This sponsorship is aimed at giving Incyte access to providers.

iv. Other OncLive funding:

1. November 27, 2017 - $240,000 for "OncLive: State of Science".
2. December 5, 2017 - $15,000 for "Chemo Foundation Sponsorship"
3. December 11, 2017 - $25,000 for "Non-CME Speaker Program – 2nd Annual School of Nursing Oncology Meeting".

g. January 11, 2018 - Request for $236,000 for the Cancer Support Community for "MPN Social Platform Support".

i. This funding was presumably provided to instruct cancer patients on how to access and utilize the Internet related to their care. However, Incyte received a tremendous benefit – access to the patients and their data.

ii. This request was budgeted to Incyte's Public Relations Department.

[4] Mr. Tunstall is not a sales representative for Incyte; he works in the company's Marketing department.

h. January 29, 2018 - Jennifer Antonacci, a Communications Director at Incyte, requested a charitable contribution of $50,000 for the Patient Empowerment Network for an "Ask the Expert" program.

i. This request was budgeted to Incyte's Public Relations Department.

C. Incyte Employed "Nurse Educators" To Promote Jakafi To Prescribing Physicians And Their Staff, And To Promote Directly To Patients To Induce Them To Utilize Jakafi In A Form Of "White Coat Marketing"

94. In this scheme, Incyte deployed "nurse educators" to recommend Jakafi to prescribing physicians, as well as directly to patients, thereby blurring the lines between independent medical advice and sales.

95. Incyte employs nurses to help promote Jakafi and obtain easier access to prescribers who are oftentimes skeptical of sales representatives, and, as a consequence, restrict or deny access to such representatives.

96. Incyte refers to these nurses as "Oncology Nurse Educators" (ONEs). Upon information and belief, Incyte employs approximately 12-14 ONEs. At the time of Relator's termination, Incyte has plans to expand this program quickly.

97. Prior to 2015, ONEs were hired and staffed as third-party employees. Beginning in or around 2015, the ONEs were transitioned to full-time Incyte employees.

98. In or around 2016, management and control of the ONE program was transferred from Incyte's medical organization to the Company's commercial division.

99. Incyte believed that ONEs were likely to be viewed by prescribers as better credentialed and more credible than traditional drug representatives, and, thus, more likely to gain access to prescribers and their staff.

100. The Office of Inspector General, Department of Health & Human Services ("HHS-OIG") refers to the practice of utilizing healthcare providers, such as nurses, to promote particular drugs as "white coat marketing", and has warned against the practice:

> The fraud and abuse risks are compounded where . . . a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services—especially when marketing to their patients.

OIG Op. 11-08 (June 14, 2011) (available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf).

101. Incyte's ONEs recommended Jakafi to doctors and patients alike. Thus, Incyte violated the AKS, and, in turn, the FCA.

102. Incyte knew that the Company's ONEs could not openly operate as sales representatives for at least three reasons:

- Prescribers would likely limit ONE (e.g., nurse) access in the same manner that drug representative access was limited, if the prescribers deduced that the ONEs were company-driven;
- Similarly, if the prescribers speculated the ONEs were nothing more than drug representatives in disguise, the prescribers would discount the ONEs "unbiased" recommendations; and
- OIG-HHS has identified "white coat" marketing as particularly suspect.

103. In an attempt to circumvent the law, Incyte contrived programs, including Voices of MPN and INFOCUS Patient Education Sessions, that would act as a cover for the ONEs, seemingly distinguishing them from drug representatives and enabling them to appear independent.

104. Incyte's ONEs also engaged in direct marketing to patients.

105. Incyte designated the nurses as "educators" who, instead of being paid to recommend drugs, were purportedly there to promote free educational services to patients.

106. Incyte ONEs promoted Jakafi directly to myeloproliferative neoplasms (MPN)[5] patients. As in their dealings with prescribers, by purporting to educate patients, "white coat" ONEs would be in a prime position to recommend and promote Jakafi directly to MPN patients.

107. These encounters were direct nurse-to-patient contacts that, in general, took place at lunch or dinner programs, community events and health fairs.

108. For example, Voices of MPN is described by Incyte as follows:

> Join us for a live, in-person learning event in your area that is **specifically designed to help patients** take a closer look at the different types of myeloproliferative neoplasms (MPNs), a group of rare blood cancers. It is your chance to ask questions, meet with others who share your condition, and get support.

(underline added, emphasis in original).

109. However, the Incyte ONEs were not unbiased educators, but biased "white coat" marketing representatives:

- The ONEs received sales training from Incyte;
- The ONEs were actively used by Incyte to drive sales;
- The ONEs, during their presentations at patient programs, routinely made reference to specific hematologists and oncologists to direct business to these health care providers; and
- The ONEs engaged directly with patients to promote Jakafi.

[5] Myeloproliferative neoplasms are a group of rare blood cancers in which the body produces too many or too few mature blood cells. These diseases include MF, PV and Essential Thrombocythemia (ET). Jakafi is not approved for use in patients with ET. However, the Voices of MPN website, which is managed and trademarked by Incyte, contains a prominent link and information about ET. *See* https://www.voicesofmpn.com/

110. By offering to educate patients and gaining access to individuals suffering from MPNs, ONEs were in a prime position to recommend and promote Jakafi directly to these patients.

111. Medications are an essential part of MPN disease management. Nurses cannot truly educate patients about MPNs without including a discussion of the medications available to treat that disease.

112. Thus, a true nurse educator's role would inherently include a discussion of the various treatment options for MF or PV. However, Incyte ONEs focus solely on the benefits of Jakafi.

113. The Incyte ONEs generally did not discuss competing drugs or treatments.

114. "Education" programs organized and run by ONEs are routinely attended by other ONEs and Incyte management personnel from Incyte's headquarters.

115. Moreover, physician calls and new patient training metrics were used to determine Incyte ONEs' compensation, thus tying their compensation to the volume or value of referrals.

116. Sales calls to prescribing physicians and the number of patient training sessions are sales metrics used by Incyte management for the ONEs. These metrics do not measure, in any meaningful way, patient health outcomes or treatment efficacy, but rather, related to new patient prescriptions and prescription refills.

117. Various ONEs describe their positions as follows, even though such statements are exaggerated:

- "As an Oncology Nurse Educator with Incyte, Becca is passionate about educating her patients to empower them and positively impact their lives.

Becca is humbled by the opportunity to interact with patients and share her knowledge of MPNs with them."

- "In her role as an Oncology Nurse Educator with Incyte, Robin relishes . . . seeing patients use the information from these programs to make informed decisions about their care."

- "Jon enjoys his role as an Oncology Nurse Educator with Incyte and conducting meetings with patients. His focus is to promote education by helping patients and their caregivers understand MPN diseases."

- "In his current role as an Oncology Nurse Educator for Incyte, he is promoting knowledge and comprehension of the MPN disease states. This is accomplished by providing education to healthcare professionals and patient advocacy groups."

See https://www.mpnpatientevent.com/nurse-profiles/ (web page includes the note "Voices of MPN and the Voices of MPN logo are registered trademarks of Incyte").

D. Incyte Made Numerous Charitable Contributions To Purportedly Independent Charitable Foundations That Were Actually Conduits To Patients To Pay The Patients' Copays For Jakafi Prescriptions.

118. Since 2014, Incyte has provided tens of millions of dollars to various copay assistance foundations and patient assistance funds (the "Foundations") it directs, manages, and/or coordinates with, including Patient Access Network Foundation ("PANF") and Chronic Disease Fund, Inc. d/b/a/ Good Days ("Good Days").

119. The Foundations manage patient assistance funds that provide direct financial assistance to qualified patients, assisting them with prescription drug co-payments their insurance requires relative to their diagnosis.

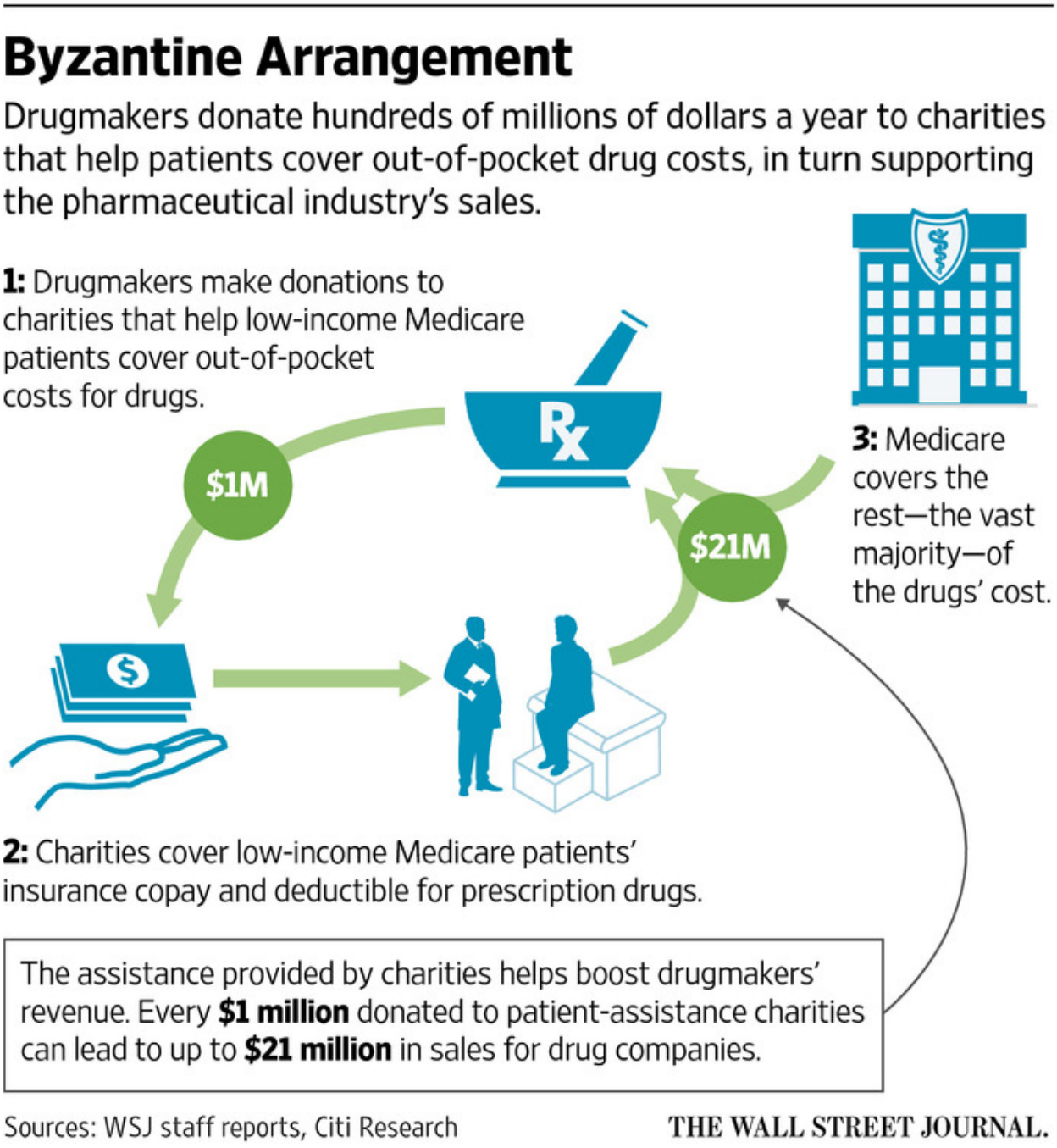
120. Incyte also has its own internal program, IncyteCARES (**C**onnecting to **A**ccess, **R**eimbursement, **E**ducation and **S**upport), to direct patients to Jakafi as a treatment and/or to patient assistance programs funded by Incyte.

121. Incyte describes the Incyte CARES program as follows:

> To help ensure that all eligible MF and PV patients have access to JAKAFI, we have established a patient assistance program called IncyteCARES (CARES stands for Connecting to Access, Reimbursement, Education and Support). IncyteCARES helps ensure that any patient with intermediate or high-risk MF or uncontrolled PV who meets certain eligibility criteria and is prescribed JAKAFI has access to the product regardless of ability to pay and has access to ongoing support and educational resources during treatment. In addition, IncyteCARES works closely with payers to help facilitate insurance coverage of JAKAFI.
>
> * * * * *
>
> Incyte CARES is a support program for people taking Jakafi. IncyteCARES provides a single point of contact through a registered nurse, Oncology Certified Nurse (OCN®), to assist eligible patients in obtaining access to Jakafi and to connect them with continuing support and resources.

122. Incyte's payments to these Foundations were not charity for MPN patients generally, but rather a way to funnel copay assistance funds to patients prescribed Jakafi.

123. The Wall Street Journal recently described the arrangement as follows:



Jonathan D. Rockoff, U.S. Probe Sheds Light on Charities' Role in Boosting Drug Sales, *The Wall Street Journal* (June 11, 2017), available at https://www.wsj.com/articles/u-s-probe-sheds-light-on-charities-role-in-boosting-drug-sales-1497000601.

124. Incyte made donations to the various Foundations as a conduit to pay the copay obligations of thousands of Medicare patients taking Jakafi, and to eliminate price sensitivity of patients purchasing or physicians prescribing Jakafi, and to induce those patients to request and/or purchases Jakafi.

125. It was in Incyte's financial interest to assist with a Medicare patient copay if, as a result, Incyte got back the Medicare payment portion (e.g., a significant portion of a Jakafi prescription cost).

126. In order to generate revenue, and instead of giving away Jakafi for free to Medicare patients who may have met the financial qualifications of a free drug program, Incyte worked to transition some portion of these patients to certain foundations which covered the patients' Medicare copays and caused Medicare claims to result from the filling of the patients' Jakafi prescriptions.

127. In connection with this initiative, Incyte made contributions to the various Foundations and, in turn, received data from the Foundations confirming that the Foundations funded the Medicare copays of Jakafi patients.

128. Upon information and belief, the transfer of data between Incyte and the Foundations was aided and supported by Incyte's business relationship with The Lash Group, a patient support services company that is a subsidiary of AmerisourceBergen.

129. In deciding whether and how much to donate to the Foundations, Incyte considered the revenue it would receive from prescriptions for Medicare patients who received assistance from the Foundations to cover their copays for Jakafi.

130. Incyte used data from the Foundations to confirm that Incyte's revenue far exceeded the amount of Incyte's donations to the Foundations.

131. The funding and subsequent distributions, including the amount, timing and release of the funds, by Incyte to the Foundations is controlled by the commercial side of Incyte, including Hervé Hoppenot (CEO, President and Chairman), Barry Flannelly (Executive Vice-President and General Manager, U.S.) and Eric Vogel (Vice President of U.S. Sales).

132. At the same time, Incyte had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their copays for Jakafi. Instead, in order to generate revenue from Medicare and to induce purchases of Jakafi, Incyte referred Medicare patients prescribed Jakafi to the Foundations, which resulted in claims to federal healthcare programs to cover the cost of the drugs

133. Incyte's patient education materials identifies the Foundations and promotional materials distributed by Incyte's sales representatives make reference to the program. Sales representatives are also encouraged at speaker programs to identify the Foundations to attendees.

134. Certain INFOCUS Patient Education or Voices of MPN promotional materials publicized the Foundations, *see infra*, as part of the presentation:

135. Similarly, part of the IncyteCARES sales script includes the following:

> IncyteCARES is a free support program for people taking Jakafi. We help patients, caregivers, and loved ones by offering support and resources you might need during treatment. . . . What we can offer is:
>
> - Access to financial support to help pay for Jakafi if you need help and you're eligible.
>
> - We can also connect you with various organizations that can sometimes help you with copayments for your medicine, transportation costs, and finding educational and emotional support resources if you need those.
>
> - If you need help understanding or managing your insurance coverage for Jakafi, I can assist with that.

136. The same sales script contains the following text for an Incyte sales representative to use:

> **Copay/Coinsurance assistance**
>
> Your copay or coinsurance is the money you have to pay out of your own pocket for medicine, aside from what your insurance plan covers. If you find that your copay or coinsurance cost is more than you can afford, IncyteCARES

> can connect you with programs that offer financial help with those costs if you qualify. If you have commercial or private insurance, you might qualify for our copay card program, for instance. If you have government insurance, you wouldn't be eligible for that program, but you might have other options we can talk about. For instance, you might qualify for medication copay assistance from organizations like the Chronic Disease Fund or Patient Access Network, also known as PAN

137. Even a scholarly article funded by Incyte identified IncyteCARES, Goods Days and PANF as "[o]organizations offering assistance for qualifying patients with myelofibrosis." Knight, et al., Managing Patients With Myelofibrosis in the Era of Janus Kinase Inhibitors, J ADV PRACT ONCOL 2015;6:532–550 (vol. 6, no. 6; Dec. 2015). The article stated that Good Days could offer "copay assistance" and PANF could "help to overcome financial and other barriers." *Id.*

138. Similarly, the MPN Research Foundation, an organization that has received hundreds of thousands of dollars from Incyte, *see supra* ¶ 93(c), states that PANF "offers co-pay assistance for patients who need it. Jakafi is one of the medications they are offering assistance with currently." *See* http://www.mpnresearchfoundation.org/Drug-reimbursement-for-approved-drugs (emphasis added).

139. Examples of Incyte's donations to the patient assistance programs at the Foundations supported by Incyte include:

a. January 2015 - Incyte made a donation to CancerCare in the amount of **$50,000** for "2015 Patient Access & Engagement Report."
    i. Funding was requested by David Dubinski, Incyte's Head of Patient Advocacy.
    ii. The payment was designated as a budget item to Incyte's Marketing department.
    iii. CancerCare is a national organization that provides free, professional support services including counseling, support groups, educational workshops, publications and financial assistance to individuals affected by cancer.

b. June 2016 – Incyte made a **$15,400,000** donation to the Patient Assistance Network Foundation ("PANF").

   i. This donation was approved on June 27, 2016.

   ii. Jennifer Vito, *see infra* ¶¶ 165-167, handled this "charitable contribution".

   iii. Incyte described the donation as "disease state fund supporting patients with MPN disorders" and it was designated as a budget item to Market Access.

   iv. PANF describes itself as an independent, national 501(c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic and rare diseases with the out-of-pocket costs for their prescribed medications. *See* https://panfoundation.org/index.php/en/. *See also* HHS OIG Opinion 07-18 (2007). *See infra* ¶¶ 141-148.

c. August 2016 – Incyte made a donation to CancerCare in an amount described as "**$500,000 to $20,000,000**".

   i. Incyte described the donation as "[c]ontribution for co-pay assistance foundation" and it was earmarked to Market Access.

   ii. The payment was approved on August 10, 2016 and the "agree[] signed by Barry [Flannelly] and CancerCare on 9/23."

d. December 2016 - Incyte made a **$44,000,000** donation to PANF for the year 2017.

   i. This donation was approved by Barry Flannelly and Hervé Hoppenot, and CEO Hoppenot was to "sign agreement [on] 12/19".

   ii. Amy Blithe, a Director in Incyte's Medical Affairs division, handled this foundation "sponsorship".

   iii. This payment was designated as a budget item to Incyte's Commercial Operations division.

e. 2016 - Incyte made a **$6,250,000** donation to the Chronic Disease Fund, Inc. d/b/a Good Days, which was approved by Barry Flannelly.

   i. Good Days describes itself as an independent 501(c)(3) non-profit organization and patient assistance organization. Donations to Good Days are made through a number of sources in and out of the healthcare industry, including corporate and individual contributors. *See* https://www.mygooddays.org/. *See infra* ¶¶ 149-159.

   ii. The donation was requested, and presumably approved, by Barry Flannelly.

   iii. It was described as "2017 Sponsorship of Patient Assistance Fund" and earmarked to Incyte's Commercial Operations division.

140. As recently as September 2018, Incyte management discussed that Incyte was preparing to fund several foundations with an additional $39 million in 2019.

141. During the same meeting, Chief Compliance Officer Dailey noted that Incyte's current funding rate placed the company "in the top 5" of funded amounts by companies to foundations and their attendant patient assistance programs, and "with the additional 39 (million), we will be in the top 3".

142. At the same meeting, Barry Flannelly suggested that Incyte begin to internally refer to "US Co-Pay Foundations" as "Independent Charitable Foundations" in order to hide their true purpose.

143. Other attendees at this meeting included Relator, Tracey L. Basler (Incyte, Executive Director, Global Privacy Officer), Ronald Falcone, Ph.D. (Vice President, Regulatory Affairs), Samantha Jones, (Sr. Director, Corporate Counsel), Steven H. Stein, M.D. (Chief Medical Officer), Paula J. Swain (Executive Vice President, Human Resources), and Paul Trower (Vice President, Finance and Principal Accounting Office).

144. The donations to various Foundations are not managed by Incyte's "Charitable Contribution Committee". Rather, donations to the Foundations is directed by Hoppenot, Flannelly and Vogel. Nor are the contributions approved or regulated by Incyte's Compliance Department.

Patient Assistance Network Foundation or PANF

145. PANF is a 501(c)(3) non-profit organization and patient assistance organization with its headquarters in Washington, D.C.

146. PANF operates funds that pay the copays of certain patients, including Medicare patients.

147. Incyte made donations to PANF and used PANF as a conduit to pay the copay obligations of thousands of Medicare patients taking Jakafi, to eliminate price sensitivity of patients purchasing or physicians prescribing Jakafi and to induce the patients' purchases of Jakafi.

148. In addition, Incyte received data from PANF confirming PANF funded the Medicare copays of Jakafi patients. Upon information and belief, this information included data detailing how many patients on Jakafi PANF had assisted, how much PANF had spent on those patients, and how much PANF expected to spend on those patients in the future.

149. Incyte received this information through funding requests, telephone calls and meeting reports, as well as direct contact with PANF's management.

150. Incyte used this information to budget for future payments to PANF and to confirm that its contributions to PANF were sufficient to cover the copays of patients taking Jakafi.

151. PANF advertises on its website that it provides reimbursement for Jakafi as a "covered medication", and its Annual Report identifies MPNs (including MF, PV and ET) as covered under its "Assistance Programs." *See* https://panfoundation.org/index.php/en/patients/medications-covered.

152. In 2017, PANF provided more than $347 million in assistance to more than 262,500 patients. PANF reported that it received contributions of more than $525 million in 2017.

Chronic Disease Fund d/b/a Good Days

153. Chronic Disease Fund, Inc. d/b/a Good Days is a 501(c)(3) non-profit organization and patient assistance organization with its headquarters in Plano, Texas.

154. Incyte made donations to Good Days and used Good Days as a conduit to pay the copay obligations of thousands of Medicare patients taking Jakafi, to eliminate price sensitivity of patients purchasing or physicians prescribing Jakafi and to induce the patients' purchases of Jakafi.

155. Good Days, a non-profit that Incyte funds, specifically provides reimbursement for MF and PV, and identifies Jakafi as a "covered medication". *See* https://www.mygooddays.org/patients/diseases-covered/myeloproliferative-diseases.

156. The Goods Days "Eligibility Criteria" for MF and PV includes "Patient is required to have valid Medicare or Military insurance coverage." *See id.*

157. The National Cancer Institute (NCI) identifies 26 unique drug formulations that have been approved by the FDA for myeloproliferative neoplasms. *See* https://www.cancer.gov/about-cancer/treatment/drugs/myeloproliferative-neoplasms.

158. Good Days affirmatively confirms that "[u]nder our copay assistance programs, we cover a specific set of drugs for each diagnosis." *See* https://pnp.mygooddays.org/Programs.

159. For myeloproliferative neoplasms, including MF and PV, Good Days only covers five of these drugs or formulations. *See* https://www.mygooddays.org/patients/diseases-covered/myeloproliferative-diseases.

160. Jakafi, manufactured by Incyte, is one of the five drugs listed as reimbursable by Good Days. *See id.*

161. Incyte received data from Good Days confirming Good Days funded the Medicare copays of Jakafi patients. Upon information and belief, this information included data detailing how many patients on Jakafi Good Days had assisted, how much Good Days had spent on those patients, and how much Good Days expected to spend on those patients in the future.

162. Incyte received this information through funding requests, telephone calls and meeting reports, as well as direct contact with Good Days' management.

163. Incyte used this information to budget for future payments to Good Days and to confirm that its contributions to Good Days were sufficient to cover the copays of patients taking Jakafi.

164. Pharmaceutical manufacturers are prohibited from paying Medicare patient copays. Incyte used these "purportedly independent" patient foundations (e.g., Good Days and PANF) as conduits to do just that.

165. Moreover, Incyte acquired and utilized the Foundations' data on patients using Jakafi and similar drugs and the charities' spending on those patients. Indeed, upon information and relief, the Foundations were required to provide Incyte with such data as part of the contractual arrangement between Incyte and the Foundations.

166. Incyte then, among other things, used the data to budget future donations to the Foundations.

167. Further, Incyte management consistently shared this data with its sales force, including the company's ONEs. For example, Incyte would identify the Foundations and the donation amounts during national sales meetings and via other, more regular teleconference and communications with the Oncology Business Directors and sales representatives.

168. There was a lack of independence between Incyte and the Foundations it supported; moreover, the transactions between Incyte and the Foundations it supported were not at arms-length.

169. For example, Jennifer Vito, a former Incyte Senior Director, Market Access and Patient Support Services, directed Catherine "Cass" Nelson, an Associate Director of

Commercial Analysis at Incyte, to proactively contact several foundations to provide assistance in developing the Foundations' budgets so that Incyte could better understand the Foundations' processes and financial needs.

170. Upon information and belief, this conduct began during 2015 and 2016.

171. Vito was directed to use this approach by Barry Flannelly. At that time, Incyte was trying to understand how to better fund the Foundations, so Flannelly directed Vito to have Nelson reach out to the Foundations to work with budgets.

172. Additionally, Kimberly Morelos, an Associate Director in Incyte's Patient Access department, was assigned to handle the constant interactions and communications between Incyte and the Foundations it supported. Moreover, it was common for Flannelly to call the Foundations himself with questions.

173. At no time has Incyte made any of the following adjustments to its policies and procedures relating to support of "independent" Foundations:

a. Incyte did not have or establish an independent group within the company, separate from the commercial function, that had sole responsibility for budgeting, approving donations, and interacting with and communicating with independent third-party patient assistance programs;

b. Incyte did not have or establish a budget process that was independent from the commercial organization to review, approve and allocate annual and supplemental donations to independent third-party patient assistance programs;

c. Incyte did not have or establish a written, standardized, and objective criteria for donations and/or implement enumerated terms in written donation agreements with independent third-party patient assistance programs; and/or

d. Incyte did not have or establish a review program that would annually audit donations to independent third-party patient assistance programs.

174. Relator contends that Incyte's misconduct is very similar to conduct described in recent DOJ settlements with Actelion Pharmaceuticals, Inc. (December 2018), Pfizer, Inc. (May 2018) and United Therapeutics (December 2017).

175. Incyte has maintained, and continues to maintain, close contact with the Foundations, including PANF, Good Days and CancerCare.

176. Donations provided to the Foundations were not ad hoc. Instead they were based on contractual arrangements (specific to disease state), committing Incyte to donate designated amounts to designated disease funds. Addendums were frequently entered to ensure all co-pays would be funded as co-pay projections changed.

177. In return, the Foundations routinely provided Incyte with both with co-pay forecasts for the following year as well as co-pay utilization. Indeed, the contracts between Incyte and the Foundations require the Foundations to regularly produce status reports to Incyte with information on the number of applicants, average amounts of co-pays, total amounts paid out, and the amount of Incyte's donation that remains available for use.

178. In other words, Good Days, CancerCare and PANF provided Incyte with the information it needed to be sure it would fully fund all co-pays needed for Jakafi, and that it successfully aligned its funding to achieve this goal.

179. Finally, Incyte knows there are other products approved for MF and PV. Those products are older, available generically and are significantly less expensive than Jakafi.

180. Thus, Incyte has a sense of urgency to keep its funds flowing to the Foundations in order to ensure that the Foundations primarily subsidize and underwrite Jakafi prescriptions.

181. Moreover, the OIG-HHS has issued guidance (in the form of a Supplemental Special Advisory Bulletin) on pharmaceutical companies' "indirect remuneration to patients"

through "contributions to PAPs" (patient assistance programs) operated by independent charities. *See* http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf. Although the Bulletin focuses on the charity as the actor, rather than a funding pharmaceutical company, it is nonetheless instructive.

182. This Bulletin noted that "[i]f a donation is made to a PAP to induce the PAP to…arrange for the purchase of the donor's federally reimbursable items, the [AKS] statute could be violated." *See id.* The OIG-HHS expressed particular concern regarding situations where non-profits "define[d] their diseases funds so narrowly that earmarking effectively results in a donor's subsidization of its own products." *See id.* A charity may not permissibly "function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients." *See id.*

183. Similarly, Incyte funds the Incyte Charitable Giving Foundation ("ICGF").

184. ICGF is a private foundation and provides Incyte with an alternative way to provide funding to advocacy, patient and other types of community groups.

185. Like IncyteCARES, the funding and subsequent distributions by ICGF is controlled by the commercial side of Incyte, including CEO Hoppenot, Flannelly and Vogel.

186. Consistent with a number of other areas at Incyte, ICGF lacks a requisite level of controls, oversight and monitoring.

E. Incyte Has Employed A Number Of Financial Inducements To Stimulate The Sale Of Jakafi Through GPOs At The Expense Of Government Healthcare Programs

187. Group Purchasing Programs (GPOs) are purchasing intermediaries between healthcare providers – mostly hospitals – and vendors of medical and pharmaceutical products and services.

188. Providers use GPOs because GPOs tend to take on the administrative burden of negotiating contracts, and they are seen as having better bargaining power given their ability to pool purchasing.

189. GPOs are funded through an administrative fee charged to the vendors, which are permitted by a statutory exception and safe harbor under the AKS. To fall within the GPO safe harbor, the administrative fees must meet certain requirements; for example, the administrative fees must be 3 percent or less of the purchase price or the contract must specify the amount or maximum amount that each vendor will pay.

190. GPOs are also allowed to distribute these fees to their healthcare provider customers through rebates and discounts. Hospitals are then required by the discount safe harbor to report the revenue from GPOs on their cost report submitted to CMS.

191. This funding structure involves an inherent conflict -- GPOs should negotiate the lowest rate for their customers; however, because they are funded through administrative fees that are a percentage of the contract costs, their incentives are not necessarily to seek the lowest price possible.

192. Incyte participates in GPOs, and pays $12,000+ per program for product access discussions to GPO employees.

193. Incyte pays in excess of $100,000 per GPO per month for ongoing product access.

194. Incyte further pays hundreds of thousands of dollars to GPO for various types of sham marketing and product pull-through programs (e.g., Cardinal summits, market research, chart reviews, etc.).

195. Incyte utilizes “administrative fees” within GPO contracts as another aspect of paying for product access.

196. These financial inducements to GPOs encourage the GPOs to place Jakafi on the preferred drug formulary, which can substantially increase the sales volume for a drug.

F. Incyte Has Employed Several Other Schemes Related To Its Marketing And Promotion Of Jakafi

197. When a certain pharmaceutical lawsuit (*Amarin Pharma v. FDA*) settled in August 2015, Incyte began a comprehensive review of all materials and data being utilized in the promotion of Jakafi, specifically data that Incyte felt was "truthful and non-misleading."

198. Much of this material was not approved by the FDA for inclusion in the labeling or promotion of Jakafi. In fact, as part of Incyte's "Big Ideas" initiatives, the company created a workstream entitled "Truthful & Non Misleading", which was led by Ankur Shah, Director, US Medical Affairs, and Thomas Barrett, Director, US Market/Product Strategy. The objective of the project was to locate new material for use in the marketing and promotion of Jakafi.

199. In an attempt to minimize risk, the "truthful and non-misleading" standard that was formerly adhered to by Incyte included certain statements about the limitation of data that sales representatives were discussing (*e.g.*, size of cohort, duration of trial, speculation around what certain day may/may not be clinically meaningful, etc.).

200. Indeed, at a meeting on October 4, 2018, Incyte's CEO, Hervé Hoppenot, made statements that included language similar to "off-label is not a legal question, it is a question of whether it is truthful". This statement was told to Relator by Chief Compliance Officer Dailey, who attended the meeting.

201. Incyte has recently revised its approach to marketing and promotion, and plans to begin using, during the promotion and marketing of its products, data from the RESPONSE clinical trial specific to quality of life and how patients "feel" without informing the prescriber of

limitations relating to the trial and this data.[6] Historically, Incyte pursued approval for the use of this data in promotion and was directed by the FDA that was not permissible, so the use of this information is a "sea change" from its previous practices.

202. Bryant Lim, Incyte's former Chief Compliance Officer, had previously provided direction at national meetings and teleconferences that quality of life data was not to be used in promotion as the RESPONSE trial was not adequately designed to prove Jakafi actually made patients "feel better" due to the limited duration and small patient cohort/size of the trial.

203. However, "symptom" messaging, such as "If you are on Jakafi, you will feel better." is now be the norm at Incyte, even though, as of October 2018, there had not been any compliance training or sales classes on how to present this new messaging.

204. Similarly, Incyte sales representatives and ONEs also were provided messaging for delivery to healthcare providers and patients (critical for the ONEs) as it relates to the IncyteCARES program and the associated success of getting a patient on Jakafi if they were enrolled in IncyteCARES, messaging like "We [Incyte] will find a way to get your patient (or you) on Jakafi".

205. In October 2018, Lance Robinson, a Manager in Incyte's Compliance & Assurance Services department, attended an INFOCUS Patient Education session presented by an Incyte Oncology Nurse Educator ("Sales Representative 2").[7]

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[6] RESPONSE was a global, randomized, open-label Phase III study conducted at more than 90 sites. 222 patients with PV resistant to or intolerant of hydroxyurea were randomized 1:1 to receive either ruxolitinib (starting dose of 10 mg twice daily) or standard therapy (best available therapy), which was defined as investigator-selected monotherapy or observation only. *See also* Vannucchi A, et al. *Ruxolitinib versus Standard Therapy for the Treatment of Polycythemia Vera.* THE NEW ENGLAND JOURNAL OF MEDICINE. 2015 372:5 (published results from the Phase III RESPONSE clinical trial demonstrating that measuring Jakafi's effect on hematocrit control and reduced spleen volume in patients with PV).

[7] Sales Representative 2 is described by Incyte as "an oncology nurse who loves to teach." https://www.mpnpatientevent.com/nurse-profiles/. Sales Representative 2 is touted as a "nurse from Incyte Corporation who will be leading the Voices of MPN patient events . . .." *See id.*

206. Mr. Robinson observed several problematic issues, including the misuse of scientific data and Sales Representative 2's failure to discuss "important safety information", and reported them to Relator.

207. Thomas Barrett, Director, US Market/Product Strategy, also attended the presentation and informed Mr. Robinson that Sales Representative 2 was not required to cover the safety information.

208. Mr. Robinson also observed several Incyte ONEs refer to Ruben Mesa, M.D., a hematologist with significant financial ties to Incyte, in the context of "being an expert" and that patients in attendance at these programs should "go see Dr. Mesa."

209. Mr. Robinson made similar observations after attending an Investigator meeting sponsored by Incyte and hosted by Philomena Colucci, DO, a Senior Medical Director, U.S. Medical Affairs, concerning the REVEAL study.[8]

210. Incyte's compliance department was only permitted by management to monitor approximately 10-15% of non-branded patient programs and 20-25% of branded patient programs.

211. Similarly, compliance only monitored approximately 5-8% of HCP speaker programs.

212. Each year, Relator had sought to increase the number of monitored speaker programs and hire headcount for this specific task, but the initiative was never approved by Incyte's Compliance Committee.

[8] The REVEAL (P**r**ospective Obs**e**rvational Study of Patients with Polycythemia **V**era in US Clinic**al** Practices) study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population (patients ≥ 18 years old) of men and women who have clinically overt polycythemia vera (PV) and are being followed in either community or academic medical centers in the United States. *See* https://www.revealpvstudy.com/.

213. During these discussions within the Compliance Committee, Barry Flannelly routinely verbalized his lack of support for monitoring, indicating that "we should be doing less, not more monitoring" and that he "doesn't understand why we do ride-alongs."

G. Incyte Underreports Its Payments To Providers In Violation Of The Sunshine Act

214. Since August 2013, the federal Physician Payments Sunshine Act ("Sunshine Act") has required manufacturers of drugs, medical devices, and biologicals that participate in Government Healthcare Programs to track and then report certain payments and items of value given to physicians and teaching hospitals. Manufacturers submit these reports to CMS on an annual basis.

215. In 2016, Incyte reported general payments of $5,633,720.77 for 12,261 transactions.

216. In 2015, Incyte reported general payments of $5,252,354.04 for 12,257 transactions.

217. In 2014, Incyte reported general payments of $3,996,071.83 for 11,173 transactions.

218. However, Incyte knowingly underreports its payments to doctors in violation of the Sunshine Act.

219. As discussed *supra*, Incyte does not consistently track participation in programs (*i.e.*, no consistent utilization of sign-up sheets, frequent use of "Did Not Eat" on sign-up sheets by representatives to conceal meals consumed by prescribers, etc.).

H. Defendant Knew Its Conduct Resulted In False Claims

220. In violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and various state False Claims Acts, Defendant is submitting, or causing to be submitted, claims for payment to

federal government-funded programs including, without limitation, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration.

221. Defendant was aware it was causing providers to submit false claims.

222. Defendant secured substantial annual revenue as a result of its fraudulent schemes. Indeed, fraudulent practices by pharmaceutical companies cost the U.S. Government and the *Qui Tam* States and Cities hundreds of millions of dollars in medically unnecessary prescriptions every year.

223. The Defendant has not taken action to notify the U.S. Government and/or the *Qui Tam* States and Cities of these fraudulent schemes and practices or to identify or return any overpayment received from Government Healthcare Programs.

I. Incyte Retaliates Against Relator And Terminates Him

224. Relator Dillon began his employment with Incyte on January 5, 2015, as the Senior Director, Compliance Risk Assurance and U.S. Compliance Lead.

225. Relator has had a 20-year career in the pharmaceutical industry, and has managed and implemented Corporate Integrity Agreements ("CIAs") at several different international pharmaceutical companies. Accordingly, Relator is familiar with conduct that violates the FCA and AKS.

226. As demonstrated by interim and written annual performance reviews and the receipt of associated financial and stock incentives, Relator Dillon's performance at Incyte met or exceeded performance objectives with no concerns identified.

227. Indeed, in February 2018, Relator was informed by his superior, during his annual performance review, that Relator's performance had met expectations and he was on track for

promotion to Executive Director in 2019.

1. Relator Is Retaliated Against for Demanding, and then Introducing New Compliance Guidelines

228. During the course of his career at Incyte, Relator had several discussions with his superiors, including both Jill Dailey, who was Incyte's Vice President and Chief Compliance Officer from early 2017 through the present, and Bryant Lim, who served as Incyte's Chief Compliance Officer from 2014 through 2017, concerning a variety of misconduct and potential FCA violations that was occurring within Incyte's commercial and sales organizations, including those illegal activities and misconduct described more fully above in the Second Amended Complaint.

229. For example, Relator specifically recalls discussing several ongoing, illegal activities and transgressions with Dailey in March 2017 during the first few weeks of her tenure at Incyte, in order to update her and help her understand the compliance efforts at Incyte.

230. These discussions included

- Incyte's improper and illegal business practices relating to the auditing of Incyte's payments and activities of U.S. Commercial Organization employees with co-pay foundations;
- observations made by compliance personnel during monitoring of speaker programs relating to the use of speaker programs and the speaker bureau to discuss off-label topics;
- monitoring and audit observations specific to the lavishness of venues utilized for speaker programs;
- the lack of healthcare provider attendees at in-office and out-of-office programs;
- the use of Incyte Oncology Nurse Educators ("ONEs") to serve as facilitators at patient programs;
- the unlawful interactions of Incyte ONEs (and other Incyte employees in attendance at these patient programs) with patients/caregivers/family; and

- the general lack of documentation and standards Incyte policies and SOPs around the activities of sales representatives and marketing employees when interacting with healthcare providers, patients and patient organizations.

231. Relator's former and current superiors at Incyte did not welcome these discussions, and Relator was told repeatedly, among other things, that "we are here to support the business" and that "this is not a compliance decision, this is a business decision."

232. Retaliation directed towards Relator became heightened when Relator attempted to establish standardized disciplinary guidelines and processes for violations of Incyte policy and its Code of Conduct by sales representatives and managers of sales representatives.

233. Relator was attempting to establish standardized monitoring, processes and guidelines for the U.S. Commercial Organization consistent with the Office of the Inspector General's ("OIG") Seven Elements of an Effective Compliance Program, specifically for employees of the sales organization.[9]

234. For example, Point 2 of the OIG's Seven Elements calls for the "[d]evelopment of compliance policies and procedures, including standards of conduct." In creating these standards of conduct for Incyte, Relator repeatedly raised examples of misconduct by Incyte's sales team with Lim and Dailey, including ONEs being permitted by the company to engage with patients with no policy or SOP in place for such interactions.

235. Relator specifically recalls discussing his concerns relating to off-label marketing during speaker programs and by the speaker bureau with Dailey and Lim at various points from 2015 through his termination in October 2018. Relator informed both Dailey and Lim that the

[9] The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has promoted voluntary compliance programs for the healthcare industry. *See, e.g.*, https://www.oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf.

company's speaker programs were being used to have proactive discussions of Jakafi for off-label uses.

236. Similarly, Relator recalls that Incyte speakers and sales representatives would proactively discuss the use of Jakafi for the treatment of solid tumors even though Jakafi did not have an indication for any solid tumor conditions, including pancreatic cancer. Relator raised this issue with both Dailey and Lim at various times.

237. Relator also illustrated for Dailey that speakers had "*carte blanche* access to providers" when reporting that various speakers were discussing, without solicitation by a provider, Incyte's ongoing graft-versus-host disease ("GvHD") clinical trials. Jakafi has never had an indication for treating GvHD.

238. Relator explained to both Dailey and Lim, and others in Incyte's compliance department, that allowing ONEs to speak to patients about specific disease states outside of myelofibrosis (MF) and polycythemia vera (PV) would lead patients to raising Jakafi as a potential treatment with their providers even though Jakafi had no indication for the patient's disease.

239. Relator also recalls an Incyte Board member asking Chief Compliance Officer Dailey if there were any violations or wrongdoing that the Board needed to know about, including transgressions related to marketing. After Dailey responded in the negative, Relator reminded her of the various marketing issues he had raised with her. Relator does not believe that Dailey ever followed up with the Board member to correct her erroneous response.

240. Additionally, as explained above, Relator pushed to have 100% monitoring in place for all non-branded and branded programs with additional compliance personnel to assist with the monitoring activities. This proposal was never approved by Incyte management.

241. However, Relator was retaliated against for proposing this increased monitoring.

242. Relator also raised Incyte's activities relating to the exchange of data between the Foundations and Incyte, often using The Lash Group as a conduit.

243. Relator specifically raised this issue with Chief Compliance Office Dailey after Relator performed an unrelated audit into The Lash Group's policies and procedures relating to protection of patient's privacy and HIPAA rights.

244. After Relator's launch of the new disciplinary guidelines and processes to the US Commercial Organization, which occurred on April 13, 2018, Relator received an email message from Barry Flannelly (Executive Vice President and General Manager) on April 14, 2018 entitled "Upset". In this email, Flannelly directed Relator to "let me [Flannelly] know before you reach out or counsel anyone on my [Flannelly] team."

245. Relator responded to Flannelly's email that same day, copying Chief Compliance Officer Dailey, who was Relator's direct superior, and requested a meeting to discuss Flannelly's concerns.

246. In response, Flannelly informed Relator that any meeting would have to be a telephone call, which occurred on April 17, 2018. During the course of a brief discussion, Flannelly spoke in a threatening tone and periodically utilized expletives toward the Relator in reference to the launch of the disciplinary guidelines and process for U.S.-based sales representatives and their managers.

247. Flannelly stated that "people will leave," because of the new disciplinary processes; in referring to "people", Flannelly was referring to Incyte sales representatives and managers.

248. Flannelly also directed Relator to attend an additional meeting to discuss the

matter, which was scheduled for April 19, 2018. The April 19th meeting was to include Eric Vogel, Incyte's Vice President of Sales.

249. Relator met with Flannelly and Vogel on April 19, 2018 to discuss the issues raised in Flannelly's "Upset" email. Relator's superior (Chief Compliance Officer Dailey) was not in attendance, nor on the phone. Relator was not provided with representation from Incyte's Human Resources department.

250. During this meeting, Flannelly and Vogel repeatedly yelled and used expletives, while pounding on the conference room table regarding the launch of the new disciplinary processes and guidelines. For example, Vogel referred to the meal cap monitoring and reporting of violations by sales representatives as "expletive expletive" and told Relator that "the OIG doesn't give a [expletive] about this."

251. Flannelly repeatedly said that "this isn't going to [expletive] happen" and that he'll "take this to the [expletive] CEO [Hoppenot] and he'll [expletive] laugh at this." Flannelly also repeated his mantra from the April 17, 2018 phone conversation that, because of these new disciplinary processes, "people will leave" and added that he was concerned these new guidelines would not allow the sales organization to "make its numbers."

252. Also, both Flannelly and Vogel expressed a concern that the new disciplinary processes and guidelines were "going to impact revenue."

253. At the conclusion of the April 19, 2018 meeting, Relator told Flannelly and Vogel that Relator would discuss this matter further with Dailey when she returned from vacation. After the meeting, Relator was visibly shaken and concerned for the status of his future employment at Incyte.

254. Upon information and belief, sometime after the April 19th meeting, Flannelly met

with Maria Pasquale, Incyte's Executive Vice President, General Counsel, and the two discussed Relator. Pasquale later told Relator that Flannelly told her that "You [compliance] are here to support commercial."

255. As Dailey, Relator's superior, was unavailable and out of the office until April 30, 2018, Relator sought the guidance of his former superior, Bryant Lim, who was now Incyte's Vice President and Assistant General Counsel.

256. On or about April 26, 2018, Relator met with Lim and shared specific details and facts from the April 19, 2018 meeting with Flannelly and Vogel, and Lim responded that he was aware of the meeting. When Relator expressed interest in sending an e-mail to Jill Daley outlining and documenting what was said during the April 19, 2018 meeting with Flannelly and Vogel, Lim told Relator that such a plan was not a good idea. During this meeting, Lim referred to Flannelly as "crazy" and recommended that Relator wait until Chief Compliance Officer Dailey returned from vacation to discuss the matter further.

257. Following his meeting with Lim, Relator was excluded from key meetings and interactions with the U.S. Commercial Organization, specifically meetings involving Flannelly and Vogel. On several occasions, Relator attempted to work with Flannelly with no acknowledgement or response.

258. Similarly, when working with Lim on investigations within the sales force, Lim repeatedly cautioned Relator that during, and especially after an investigation, "Vogel {VP, U.S. Sales] will be pissed, watch out." Lim made this comment to Relator after virtually every investigation into Vogel's sales department.

259. On May 1, 2018 Relator met with Chief Compliance Officer Dailey, who had returned to the office from vacation. At this meeting, Relator informed Dailey of the April 17,

2018 phone call with Flannelly and the April 19, 2018 meeting with Flannelly and Vogel.

260. Relator specifically shared with Dailey what was said during the phone call and meeting, the behavior of Flannelly and Vogel during the phone call and meeting that violated Incyte's Code of Conduct, and Relator's concerns for his ongoing employment with Incyte. Dailey responded that she was "aware" of the meeting and told Relator that she would "handle meetings and communications with the US Leadership Team going forward."

261. At no point after the May 1, 2018 meeting between Relator and Dailey until his termination on October 26, 2018, did Dailey attempt to address Relator's concerns for the Code of Conduct violations by Flannelly and Vogel, nor Relator's fear of retaliation or intimidation by Flannelly and Vogel.

262. To further make Relator's performance difficult, Chief Compliance Officer Dailey began to purposely exclude Relator from critical meetings and discussions with the U.S. Sales leadership and Management team. Similarly, on a consistent basis, Dailey did not keep Relator apprised of critical discussions and decisions.

263. For example, Dailey excluded Relator from the launch of the U.S. Compliance Committee meeting and other key meetings. This purposeful exclusion by Dailey made Relator's role within the company very difficult.

264. On May 9, 2018, Relator was invited to a meeting held in a conference room generally used for meetings with external visitors at the Wilmington, Delaware, headquarters of Incyte. Relator, Chief Compliance Officer Dailey and Kevin Kenworthy, a representative from Human Resources, attended the meeting.

265. During this meeting, Dailey, Relator's superior, read from a document not provided, nor shown to, Relator. Dailey made several accusations that Relator repeatedly

attempted to discuss and rebut; however, each and every time Relator tried to speak, Dailey did not permit him to explain or respond.

266. Indeed, on at least three separate occasions, Relator tried to explain that the claims being made by Dailey were a direct result, and active retaliation by Flannelly and Vogel, of Relator's attempt to establish disciplinary guidelines and processes for sales representatives and their managers of the US Commercial Organization. Relator verbalized concerns and attempted to provide concrete evidence of other acts of retaliation and intimidation by Flannelly and Vogel. Relator was not permitted to speak by Dailey.

267. During the course of the May 9, 2018 meeting, HR representative Kenworthy made no attempt to understand or listen to Relator's concerns of retaliation and intimidation by members of Incyte's Executive and Senior Management teams, specifically Flannelly and Vogel. Nor did HR representative Kenworthy ask Relator any questions.

268. One day later, on May 10, 2018, Relator received an e-mail from Dailey, with a copy to Human Resources, in which Dailey stated that she "will take the lead with US LT [U.S. Leadership Team] meetings until further notice...", instructed Relator to "copy me on any communications that you will have with the US LT.", that Dailey "will put together a US Compliance Committee with the US LT to keep them updated on Compliance initiatives" (thus excluding Relator from this issue), and that Relator will not "lead or participate in any investigations impacting the US Business."

269. The email closed with Dailey stating that "You [Relator] and I will discuss what steps need to be taken from a personal development perspective to re-establish trust and credibility with the US business; and/or any follow up conversations that should take place with Eric Vogel or others in the organization."

270. The e-mail did not address, nor make reference to, Relator's concerns with retaliation and intimidation that were vocalized during the May 9, 2018 meeting with Dailey and Kenworthy.

271. With the exception of the May 9, 2018 meeting, Relator's performance at Incyte had consistently "met" or "exceeded" expectations as documented during annual performance reviews. Indeed, the comments made by Relator's superior at the May 9, 2018 meeting and in Dailey's May 11, 2018 e-mail to Relator directly contradict feedback provided by Dailey to Relator only three months before during his 2018 performance review.

272. On or about the week of May 21, 2018, Michael Purvis, Incyte's Vice President and Assistant General Counsel, commented to Relator that he had heard that "Flannelly and Vogel [expletive] hate you." When Relator asked Purvis where he had heard this, Purvis responded to Relator "Jill." At the time, Jill Dailey was Relator's superior.

273. From the April 19, 2018 meeting with Flannelly and Vogel until Relator's termination from Incyte on October 26, 2018, Relator was intentionally and knowingly excluded from key meetings and interactions by his superior and by other members of Incyte's Executive and Senior Management. During this time period, Relator received no additional guidance or assistance with his retaliation and intimidation claims from either his superior or members of Incyte's Human Resources department.

2. Relator is Excluded from A Critical Audit and Assessment of Incyte's Business

274. In or around November 2016, Chief Compliance Officer Lim announced that Huron Consulting Group, Inc. ("Huron") would be engaged by Incyte to perform an assessment relating to Incyte's activities with the Foundations.

275. Relator questioned why this project was being outsourced to Huron, given Relator's own extensive experience understanding the guidelines of biopharmaceutical/pharmaceutical manufacturers' interactions with Foundations and given Relator's responsibilities of leading Incyte's Compliance Auditing & Monitoring function.

276. Lim informed Relator that Eric Siegel, Incyte's General Counsel at the time, had decided that Huron would handle this matter, as an assessment and not as an audit.

277. Relator again questioned why a third-party without the internal working knowledge of Incyte and the Foundations was selected for this matter. Relator also verbalized his concern that this project was being conducted as an assessment as opposed to a rigorous audit. CCO Lim refused to change the company's decision to hire Huron.

278. Over the next several months, Relator requested that Lim include Relator in any status or update meetings specific to the assessment that Huron was conducting. These requests were either ignored or denied.

279. In or around June 2017, Lim communicated that the assessment by Huron was complete. Relator repeatedly asked for a copy of the assessment given his role as leading Incyte's auditing and monitoring functions. This request was consistently denied by Lim, who was now Assistant General Counsel, and Chief Compliance Officer Dailey.

280. Several weeks after Lim communicated that the assessment by Huron was complete, Relator again requested if he could be provided with a summary so that he could understand any gaps that needed to be addressed and closer. In response, Lim informed Relator that Chief Compliance Officer Dailey would assume responsibility for this project.

281. Relator then asked Dailey for a copy of report prepared by Huron relating to the assessment of the Foundations. Dailey told Relator that she was unsure if she could provide it to

him, and would check with General Counsel Siegel. Relator never received a response from Dailey.

282. Several weeks after Relator requested the Huron assessment report from Dailey, Relator checked with Dailey on the status of receiving a copy of the Huron report. Dailey responded that she had not yet read the assessment herself, but indicated that she had a copy on her desk.

283. Recognizing the potential risk to Incyte due to its risky relationship with the Foundations, Relator frequently requested a copy of the report of the Huron assessment from Dailey. However, Relator's requests were met with harsh criticism by Dailey, and meetings to discuss the report with Dailey were postponed and/or cancelled.

284. In or around January 2018, Dailey informed Relator that Aaron Maskery, a Senior Manager in the Compliance department, would be taking over responsibility for any follow-up from the Huron assessment report. Relator questioned Dailey over the selection of Maskery given Maskery's limited knowledge of the copay assistance foundations. Dailey abruptly ended the meeting and informed Relator that the decision was made.

285. Relator continued to check with Dailey on Maskery's progress regarding potential gaps identified during the Huron assessment. Dailey ignored Relator's requests for updates and eventually directed Relator to speak directly with Maskery.

286. In August 2018, Dailey sent the Huron assessment report to Relator. Upon review of the report, it was quickly evident to Relator that the assessment was incomplete, irrelevant and a whitewash. The report did not seek to understand if Incyte and its employees were engaging in improper or illegal behavior and activities with the Foundations, including activities related to Medicare patients.

287. Relator questioned the content and thoroughness of the Huron report with Dailey, and she directed Relator to address any questions to Maskery.

288. In an August 2018 meeting with Maskery to review problematic issues with the completeness of the Huron assessment report, Maskery verbalized that his work was "not urgent". Relator questioned the lack of urgency given that the Huron assessment was completed in or around June 2017, and had been lying dormant for more than a year.

289. Relator attempted to address Maskery's lack of urgency with Dailey, and, again, his requests were ignored.

290. Given Relator's knowledge of Incyte and copay assistance foundations, Relator attempted to update the inadequate matrix of open issues that Maskery had created from the Huron assessment report. Relator then attempts to obtain Dailey's approval of the updates; however, Dailey repeatedly refused to review the updates or meet with Relator on the subject. Dailey eventually told Relator to use the matrix created by Maskery.

291. Relator concluded that Dailey was retaliating against him and treating him in a hostile manner because he was raising issues that were violative of federal law and had voiced concerns about Flannelly and Vogel's conduct.

3. Relator Is Terminated in October 2018.

292. On October 26, 2018, Relator was invited to a meeting with his superior, Jill Dailey, and Darren Teeter, a Senior Director in Incyte's Human Resource department, during which Dailey asked Relator about expenses relating to business travel. Relator attempted to respond that the travel in question consisted of cancelled business trips with no reimbursement provided to Relator. Relator further attempted to show that the only reimbursement for these trips was between Incyte and its corporate travel bureau.

293. During this meeting, Relator also explained to Dailey that she could verify any trips taken by Relator and any associated expenses reimbursed by reviewing Incyte's expense reimbursement portal, specifically she could access a summary of any electronic fund transfers to Relator. After this explanation, Dailey responded, "We're not here to discuss that."

294. At the conclusion of the meeting, Relator asked Dailey if he could access and/or provide responses and/or travel information to address Dailey's concerns. Relator was told he had some time to do so; however, neither during the initial meeting nor any time thereafter, was Relator provided with any written materials specific to or revealing Dailey's concerns.

295. This initial meeting only lasted 27 minutes.

296. Following the initial meeting on October 26, 2018, Relator had a second meeting the same day with Dailey and HR representative Teeter, which lasted only seven (7) minutes. Relator was given less than 30 minutes to locate and produce relevant travel data. During this second meeting, Relator attempted to present evidence from Incyte's corporate travel bureau and expense portals that refuted Dailey's accusations.

297. However, as Relator attempted to provide substantiation to demonstrate Dailey's claims were false, he was stopped by Dailey on several occasions, who continually repeated "We're not here to discuss that."

298. At the end of this pretextual meeting, Relator was terminated by Defendant without any severance.

299. It was especially jarring to Relator, because he was wrongfully terminated after two brief meetings - 27 minutes and 7 minutes, respectively – and not provided ample time or resources to counter the company's pretextual and inaccurate claims.

300. Indeed, Dailey's inability to understand, let alone respond to, Relator's explanations demonstrated her own ignorance and lack of knowledge regarding Incyte's policies and procedures.

301. Finally, Relator's abrupt and rushed termination is in direct comparison to how Incyte has addressed and handled similar allegations and follow-on meetings with employees of the sales and marketing organizations.

302. Due to his position, Relator has first-hand knowledge and direct observation of situations when the actions of sales and marketing employees were called into question. In comparison to Dailey's handling of Relator's termination, those employees were provided several days' notice to prepare themselves, and the meetings generally last several hours. The sales and marketing employees were permitted to review any allegations and provided time during and after the meeting to respond to the allegations.[10]

303. Relator was terminated by Incyte for raising numerous compliance issues with the company's management over the course of several years.

304. Indeed, after Relator raised his concerns to Dailey, Lim, Flannelly, Vogel, Incyte subjected Relator to heightened scrutiny and criticism for conduct that he routinely performed beforehand, none of which was performance-related.

VII. IMPACT ON PRIVATE INSURERS

305. The state of California and Illinois have enacted insurance fraud prevention

[10] It is also important to note that, in cases of violations by sales and marketing employees, Incyte's compliance was only permitted to develop a recommendation for a sanction. The management of the Commercial Organization (i.e., Barry Flannelly, Eric Vogel, John Krukiel) made the final decision on whether to terminate an employee, or what type of lesser sanction the employee would receive.

statutes that permit a relator to bring a qui tam action to recover for fraudulent claims submitted to private insurance companies in those states. *See infra* Counts VI and XIII.

306. Although this Second Amended Complaint has focused on the impact of Defendant's practices on the federal and state governments, these same practices also defraud private insurance companies in the same manner that the practices defraud the federal and state governments.

307. The practices alleged herein are systematic, nationwide practices that defraud private insurance companies that reimburse prescription drugs in every state where Incyte conducts business, including California and Illinois.

VIII. CAUSES OF ACTION

COUNT I
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(A)

308. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

309. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 *et seq*., as amended.

310. During the relevant period, Defendant presented, or caused to be presented, numerous claims for payment to the United States Government and/or the *Qui Tam* States and Cities through the Government Healthcare Programs, including through Medicare and Medicaid, for the Defendant's prescription drug, Jakafi.

311. For the reasons alleged herein, many of these claims were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendant knowingly presented, and/or caused to be presented, to an officer and/or employee of the United States Government

and/or the *Qui Tam* States and Cities false and fraudulent claims for payment and approval in violation of 31 U.S.C. § 3729(a)(1)(A).

312. Defendant had actual knowledge of the falsity of these claims, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

313. The United States and the *Qui Tam* States and Cities suffered damages as a result of false claims by Defendant and are entitled to recover their losses and otherwise obtain relief available under the FCA.

COUNT II
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(B)

314. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

315. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 et seq., as amended.

316. During the relevant period, Defendant presented, or caused to be presented, numerous records and statements to the United States Government and/or the *Qui Tam* States and Cities through the Government Healthcare Programs, including Medicare and Medicaid for the prescription drug Jakafi.

317. For the reasons alleged herein, many of these records and statements were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendant knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the United States Government and/or the *Qui Tam* States and Cities in violation of 31 U.S.C. § 3729(a)(1)(B).

318. Defendant had actual knowledge of the falsity of these statements, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

319. The United States and the *Qui Tam* State and Cities suffered damages as a result of false records and statements by Defendant and are entitled to recover their losses and otherwise obtain relief available under the FCA.

COUNT III
31 U.S.C. § 3729(a)(1)(C)

320. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

321. Defendant combined, conspired, and agreed together with physicians and others to defraud the United States by knowingly causing false or fraudulent claims to be presented for payment or approval and knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, and ultimately profited from those false claims. Defendant committed other overt acts set forth above in furtherance of that conspiracy, all in violation of 31 U.S.C. § 3729(a)(1)(B), causing damage to the United States.

322. Compliance with applicable federal laws and regulations cited herein is a material condition of payment of claims for payment or approval.

323. Had the United States known that Defendant was violating the federal laws and regulations cited herein, it would not have paid the claims caused by Defendant's fraudulent and illegal practices.

324. As a result of Defendant's violations of 31 U.S.C. §3729(a)(1)(C), the United States has been damaged in a significant amount to be determined at trial.

COUNT IV
Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901

325. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

326. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901.

327. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Arkansas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

328. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

329. By reason of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT V
California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

330. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

331. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

332. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

333. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

334. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VI
California Insurance Frauds Prevention Act, California Insurance Code § 1871.7

335. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

336. Numerous privately insured California patients are prescribed and take Jakafi, a very expensive drug.

337. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as "the Act"). The Act provides a civil cause of action against any person who commits the crime of insurance fraud or who offers or pays illegal inducements or kickbacks to secure benefits under a contract of insurance. Cal. Ins. Code §1871.1(e).

338. The Act provides for civil recoveries against persons who violate the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code §1871.7(b).

339. Subsection (e) of Cal. Ins. Code §1871.7, the *qui tam* provision of the Act, was patterned after the federal False Claims Act, 31 U.S.C. §§3729 *et seq.*, and the California False Claims Act, Cal. Gov't Code §§12650 *et seq*.

340. Subsection (a) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who "knowingly employ runners, cappers, steerers, or other persons . . . to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer."

341. Subsection (b) of Cal. Ins. Code § 1871.7 provides a range of penalties for violations of Penal Code sections 549 or 550. Section 549 of the California Penal Code provides criminal penalties for anyone who: solicits, accepts, or refers any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether, the individual or entity . . . intends to violate Section 550.

342. Section 550 of the Penal Code prohibits the following activities, among others:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * * * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.
>
> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.
>
> * * * * * *
>
> (b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:
>
> (1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

> (3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

343. By virtue of the acts described in this Complaint, Defendant violated Cal. Ins. Code § 1871.7(a) by knowingly employing "other persons" to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that were the basis for claims against private insurers in the State of California

344. By virtue of the acts described in this Complaint, Defendant violated California Penal Code § 549 by soliciting, accepting, or referring business to or from individuals and entities with the knowledge that, or with reckless disregard for whether, the individuals or entities intended to violate California Penal Code §550.

345. By virtue of the acts described in this Complaint, Defendant knowingly presented or caused to be presented, false or fraudulent claims for healthcare benefits, in violation of Penal Code § 550(a).

346. By virtue of the acts described in this Complaint, Defendant also concealed and/or failed to disclose information that would have affected the rights of patients and/or providers to receive reimbursement for Jakafi, in violation of Penal Code § 550(b).

347. By virtue of these violations of California Penal Code §§ 549 and 550, Defendant violated California Insurance Code § 1871.7(b).

348. Incyte systematically and repeatedly violated the Act by providing kickbacks to healthcare providers throughout California.

349. Subsequently, each claim for reimbursement for Jakafi submitted to a health insurer represents a false or fraudulent claim for payment.

350. Relator cannot at this time identify all of the false claims for payment that were caused by Defendant's conduct. The false or fraudulent claims were presented for payment by hundreds, if not thousands, of separate entities across the State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

351. Private insurers, unaware of Defendant's fraudulent acts and the falsity of the records, statements and claims made or caused to be made by Defendant, paid and continue to pay the claims that would not be paid but for Defendant's unlawful conduct.

352. As a result of Defendant's commission of the insurance fraud described herein, the State of California and its citizens have been damaged in an amount in excess of millions of dollars, exclusive of interest.

353. The California State Government is entitled to receive three times the amount of each claim for compensation submitted by Defendant in violation of Cal. Ins. Code §1871.7.

354. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT VII
Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq*.

355. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

356. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq.*

357. By virtue of the illegal acts, as described more fully above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims involving the prescription drug Jakafi.

358. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

359. By reason of the Defendant's unlawful acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT VIII
Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

360. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

361. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

362. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

363. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

364. By reason of these payments, the Connecticut Medicaid Program has been damages, and continues to be damaged in a substantial amount.

COUNT IX
Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 *et seq.*

365. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

366. This is a claim for treble damages and civil penalties under the Delaware False Claims Act, Del Code Ann. tit. 6, § 1201 *et seq*.

367. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Delaware Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

368. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

369. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT X
Florida False Claims Act, Fla. Stat. Ann. 5 68.081 *et seq.*

370. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

371. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq*.

372. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

373. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

374. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XI
Georgia False Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

375. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

376. This is a claim for treble damages and civil penalties under the Georgia False Claims Act, Ga. Code Ann. § 49-4-168 *et seq*.

377. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

378. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

379. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XII
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 17511 *et seq.*

380. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

381. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 17511 *et seq*.

382. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving the prescription drug Jakafi.

383. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

384. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIII
Illinois Insurance Claims Frauds Prevention Act, 740 Ill. Comp. Stat. §92

385. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

386. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92/1 *et seq*. ("Illinois Insurance Fraud Act").

387. Subsection 5(a) of the Illinois Insurance Fraud Act provides for a civil cause of action for any person who commits the crime of insurance fraud or who knowingly offers or pays "any remuneration directly or indirectly, in cash or in kind, to induce any person to procure

clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer." 740 Ill. Comp. Stat. §92/5(a).

388. Pursuant to 720 Ill. Comp. Stat. §5/46-1 of the Illinois Criminal Code, a person commits the offense of insurance fraud when he or she:

> knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company . . . .

720 Ill. Comp. Stat. §5/46-1(a).

389. Subsection 15(a) of the Illinois Insurance Fraud Act provides for a *qui tam* civil action in order to create incentives for private individuals to disclose and prosecute violations of the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. §92/15(a).

390. By virtue of the acts described in this Complaint, Defendant committed the following acts, or aided and abetted the commission of the following acts, in violation of the Illinois Insurance Fraud Act:

> (a) Defendant knowingly offered or paid remuneration directly or indirectly, in cash or in kind, to induce other persons to procure clients or patients to obtain services or benefits under a contract of insurance or that would be the basis for a claim against an insurer, in violation of 740 Ill. Comp. Stat. §92/5(a); and
>
> (b) Defendant knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat.§92/5(b) and 720 Ill. Comp. Stat. §5/46-1(a).

391. Each prescription that was written as a result of Defendant's illegal marketing practices, instructions to falsify diagnosis codes to procure reimbursement, and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such prescriptions submitted to a health insurer represents a false claim for payment.

392. Relator cannot at this time identify all of the false claims for payment that were caused by Defendant's conduct. The false or fraudulent claims were presented by thousands of separate entities across State. Relator has no control over or dealings with such entities and has no access to the records in their possession.

393. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's unlawful conduct, and have been damaged thereby.

394. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by Defendant in violation of 740 Ill. Comp. Stat. §92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XIV
Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5

395. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

396. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

397. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

398. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

399. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XV
Iowa False Claims Act, Iowa Code § 685.3(2)(a)

400. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

401. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code § 685.3(2)(a).

402. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Iowa Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

403. The State of Iowa, or its political subdivisions, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid for claims that otherwise would not have been allowed.

404. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVI
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann. § 46:439.1 *et seq.*

405. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

406. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq*.

407. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

408. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

409. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVII
Maryland False Claims Act, Md. Code Ann. §2-601 *et seq.*

410. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

411. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann. § 2-601 *et seq*.

412. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

413. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

414. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVIII
Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

415. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

416. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

417. By virtue of the schemes and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

418. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

419. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIX
Michigan Medicaid False Claims Act, MCLA §§ 400.601

420. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

421. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA, §§ 400.601.

422. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

423. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

424. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XX
Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*

425. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

426. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq*.

427. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims

for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

428. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

429. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXI
New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*

430. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

431. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

432. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

433. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

434. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXII
New York False Claims Act, N.Y. State Fin. Law § 187

435. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

436. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187.

437. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving the prescription drug Jakafi.

438. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

439. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
North Carolina False Claims Act, N.C.G.S §§1-605 *et seq.*

440. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

441. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S §§1-605 *et seq.*

442. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent

claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving the prescription drug Jakafi.

443. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

444. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIV
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053

445. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

446. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053.

447. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving the prescription drug Jakafi.

448. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

449. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXV
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

450. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

451. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq.*

452. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Rhoda Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement involving the prescription drug Jakafi.

453. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

454. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVI
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* and Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

455. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

456. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.; Tenn. Code Ann. § 4-1 8-101 et seq.

457. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims

for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

458. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

459. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVII
Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq*

460. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

461. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 et seq.

462. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

463. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

464. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*

465. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

466. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-21 6.1 *et seq.*

467. By virtue of the illegal acts, described more fully above, Defendant knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

468. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

469. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIX
Washington Medicaid False Claims Act, RCW 74.66.020 *et seq*.

470. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

471. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, RCW 74.66.020.

472. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Washington Medicaid Program false or fraudulent

claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

473. The Washington Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

474. By reason of these payments, the Washington Medicaid Program has been damaged, and continues to be damaged in a substantial amount**.**

COUNT XXX
Wisconsin False Claims for Medical Assistance Act,
Wis. Stat. §§ 20.931 *et seq.*

475. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

476. This is a claim for treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq.*

477. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

478. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

479. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXI
Chicago False Claims Act, § 1-22-010 *et seq.*

480. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

481. This is a claim for treble damages and civil penalties under the Chicago False Claims Act, § 1-22-010 *et seq.*

482. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the City of Chicago Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

483. The City of Chicago Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

484. By reason of these payments, the City of Chicago Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

485. Upon information and belief, Defendant is a "city contractor" as that phrase is defined in the Chicago Municipal Code, § 1-22-030.

COUNT XXXII
District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq.*

486. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

487. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code 5 2-308.14 *et seq.*

488. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement involving the prescription drug Jakafi.

489. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims and/or statements made by Defendant, paid for claims that otherwise would not have been allowed.

490. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXIII
New York City False Claims Act
New York City Adm. Code, § 7-801 *et seq.*

491. Relator re-alleges and incorporates herein by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

492. This is a claim for treble damages and civil penalties under the New York False Claims Act, New York Adm. Code, § 7-801.

493. By virtue of the illegal acts, as described more fully above, Defendant knowingly caused to be presented to New York City false or fraudulent claims for the improper payment or approval of reimbursement for the devices identified above and used false or fraudulent records to accomplish this purpose.

494. The New York City Health and Hospitals Corporation, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

495. By reason of these payments, the New York City Health and Hospitals Corporation has been damaged, and continues to be damaged in a significant amount.

COUNT XXXIV
Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

496. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

497. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

498. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

499. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

500. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXV
Minnesota False Claims Act, § 15C.01 *et seq.*

501. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

502. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, § 15C.01 *et seq.*

503. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

504. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

505. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXVI
Montana False Claims Act, Mont. Code Ann. § 17-8-401

506. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

507. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. § 17-8-401.

508. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

509. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXVII
New Mexico Medicaid False Claims Act, N.M. Stat. § 27-14-1 *et seq.*
New Mexico Fraud Against Taxpayers Act, N.M. Stat. § 44-9-1 *et seq.*

510. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

511. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978, § 27-14-1 *et seq.*

512. By virtue of the illegal acts, as described more fully above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

513. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

514. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXVIII
Retaliation in Violation of 31 U.S.C. 3730(h)

515. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

516. 31 U.S.C. §3070(h)(1) provides that "[a]ny employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful

acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter."

517. Relator became aware of misconduct on the part of Incyte and reported it to his superiors.

518. Relator engaged in activity protected under the statute by reporting concerns about misconduct and illegal behavior which reasonably could lead to a viable False Claims Act action.

519. Relator engaged in activity protected under the FCA by voicing concerns to Defendant and its management that the actions of Incyte's agents violated FDA regulations, among other things.

520. Relator engaged in activity protected under the FCA by voicing concerns to Defendant and its management that Incyte's agents engaged in conduct that would lead it to misrepresent or omit data relating to Jakafi.

521. Relator in good faith believed that the actions of Incyte's agents and employees violated FDA regulations, among other things.

522. Incyte, including and through its management team, knew that Relator engaged in the protected activity.

523. Incyte, including and through its management team, knew that Relator's concerns implicated misrepresentations and/or omissions that would be made on Government Healthcare Programs

524. Defendant Incyte harassed, threatened, discharged, and otherwise discriminated against Relator in the terms and conditions of his employment because of his efforts to stop false

claims from being made to the government through mislabeling, improper promotion of off-label uses of Jakafi, unlawful kickbacks, and other acts described above.

525. The actions of the Defendant, through its agents, servants and employees, in, among other things, terminating Relator's employment in retaliation for having engaged in protected activity, namely, for having publicized and internally reported the Defendant's ongoing illegal actions, constituted a violation of 31 U.S.C. §3730(h).

526. Defendant discriminated against Relator because he engaged in protected activity under the False Claims Act when they subjected him to heightened scrutiny and criticism.

527. Defendant discriminated against Relator because he engaged in protected activity under the False Claims Act when they terminated his employment.

528. As a direct result of the aforesaid unlawful retaliatory employment practices and unlawful termination engaged in by the Defendant in violation of 31 U.S.C. §3730(h), Relator sustained permanent and irreparable harm, resulting in the loss of his employment, which caused him to sustain a loss of earnings, plus the value of certain benefits, plus loss of future earning power, plus back pay, front pay, and interest due thereon.

529. Because of Defendant's unlawful retaliation, Relator has suffered damages, including, lost salary, lost bonuses, the ability to purchase and/or receive Restricted Stock Units (RSUs) and/or stock options, and benefits and other economic losses in an amount that is continuing to accrue and will be determined at the time of trial

530. Because of Defendant's unlawful retaliation, Relator has suffered severe emotional distress including, but not limited to, anxiety, sleeplessness, humiliation, and loss of

enjoyment of life. He is entitled to compensation for these damages in an amount to be determined by the jury at trial.

531. Because of Defendant's unlawful retaliation, Relator has incurred attorney fees and costs and other expenses in an amount to be determined at time of trial

COUNT XXXIX
Unlawful Retaliation for Whistleblowing in Violation of Public Policy in the Commonwealth of Pennsylvania

532. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Second Amended Complaint.

533. Defendant Incyte harassed, threatened, discharged, and otherwise discriminated against Relator in the terms and conditions of his employment because he reported what he believed in good faith to be violations of law, rules and regulations to the appropriate compliance authorities.

534. The actions of Defendant, through its agents, servants and employees, in terminating Relator's position of employment in retaliation for his whistleblowing and complaints, constituted a violation of the well-established public policy of the Commonwealth of Pennsylvania that employers are prohibited from discharging an employee for his or her refusal to commit a crime or partake in the employer's unlawful actions.

535. The wrongful termination of Relator's employment by Defendant, through its agents, servants and employees, was willful, malicious, wanton and in bad faith and in reckless disregard of Relators rights and interests.

536. Because of Defendant's unlawful retaliation, Relator has suffered damages including lost salary, lost bonuses, the ability to purchase and/or receive Restricted Stock Units

(RSUs) and/or stock options and benefits and other economic losses in an amount that is continuing to accrue and will be determined at the time of trial.

537. Because of Defendant's unlawful retaliation, Relator has suffered emotional distress, including, but not limited to, anxiety, sleeplessness, humiliation, and loss of enjoyment of life. He is entitled to compensation for these damages in an amount to be determined by the jury at trial.

538. Because of Defendant's unlawful retaliation, Relator has incurred attorney fees and costs and other expenses in an amount to be determined at time of trial.

539. By reason of the willful and malicious acts of Defendant, acting as aforesaid, Relator is entitled to punitive damages in addition to compensatory damages, both of which he hereby claims of Defendant.

IX. DAMAGES

540. Relator repeat and re-allege each allegation in each of the preceding paragraphs as if fully set forth herein.

541. The FCA imposes liability on any person who

> knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim; conspires to commit a violation of the False Claims Act… or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a). Prior to 2016, the last increases to the penalties for False Claims Act violations occurred on August 30, 1999 and changed the minimum from $5,000.00 to $5,500.00 and the maximum from $10,000.00 to $11,000.00, plus treble damages. 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999). On August 1, 2016, the U.S. Department of Justice published Interim Final Rules,

which significantly increased penalties under the False Claims Act for the first time in nearly eighteen years. Now, for violations occurring after November 2, 2015, the new minimum and maximum penalties are $10,781.00 to $21,563.00 plus treble damages. 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016).

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment as follows:

A. That Defendant be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq*.; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

B. That this Court enter judgment against Defendant in an amount equal to treble (three times) the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 31 U.S.C. § 3729 prior to November 2, 2015;

C. That this Court enter judgment against Defendant in an amount equal to treble (three times) the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $10,781.00 and not more than $21,563.00 for each violation of 31 U.S.C. § 3729 after November 2, 2015, pursuant to 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016);

D. That Relator be awarded two times his lost compensation with interest thereon, as well as compensation for his emotional distress sustained as a result of Defendant's retaliation;

E. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

F. That Relator be awarded all litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law

G. The Relator and the U.S. Government recover the maximum amount under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a;

H. The Relator and the U.S. Government recover the maximum amount under the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

I. That Relator and the U.S. Government be awarded all costs of this action, including attorneys' fees and expenses; and

J. For such other and further relief as this Court may deem proper.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Relator demands a jury trial for all claims and issues so triable.

Respectfully submitted,

Dated: May 21, 2019

/s/ Brian J. McCormick, Jr.

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